

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

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (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, 2025

☐ 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 333-284064

ASCENTAGE PHARMA GROUP INTERNATIONAL
(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Cayman Islands

(Jurisdiction of incorporation or organization)

68 Xinqing Road Suzhou Industrial Park, Suzhou, Jiangsu, China
(Address of principal executive offices)

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(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(s)	Name of each exchange on which registered
American depositary shares (each representing four ordinary shares, no par value per share)	AAPG	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:

373,322,192 Ordinary Shares, par value US\$0.0001 per share, as of April 1, 2026.

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 definition 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 Exchange Act).

☐ 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

Except where the context otherwise requires or where otherwise indicated in this Annual Report on Form 20-F, all references to “Ascentage Pharma,” the “Company,” “we,” “us,” and “our” refer to Ascentage Pharma Group International, a Cayman Islands exempted company, and its subsidiaries.

PRESENTATION OF FINANCIAL INFORMATION

Our financial statements included in this Annual Report on Form 20-F are prepared in accordance with the International Financial Reporting Standards and its interpretations, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our financial statements are presented in Renminbi, or RMB and none of the financial statements are prepared in accordance with U.S. GAAP. Our fiscal year ends on December 31.

The terms “US\$,” “U.S. dollars,” “dollars” and “\$” refer to U.S. dollars and the term “RMB” refer to the legal currency of the People’s Republic of China. Unless otherwise indicated, all references to currency amounts in this Annual Report on Form 20-F are in RMB. We have made rounding adjustments to some of the figures included in this Annual Report on Form 20-F. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

Unless otherwise noted, all translations from Renminbi to U.S. dollars in this annual report are made at a rate of RMB6.9931 to US\$1.00, the exchange rate set forth for cable transfers in the City of New York, as certified by the Federal Reserve Bank of New York, on December 31, 2025. We make no representation that any Renminbi or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or Renminbi, as the case may be, at any particular rate, or at all.

FREQUENTLY USED TERMS

Key Business Terms

Unless otherwise stated or unless the context otherwise requires in this document:

“**ADSs**” refer to American depositary shares, each of which represents four (4) of our ordinary shares, no par value per share;

“**ADRs**” refer to the American depositary receipts that evidence the ADSs;

“**CCASS**” refers to the Central Clearing and Settlement System established and operated by HKSCC;

“**China**” or “**PRC**” refer to the People’s Republic of China, and only in the context of describing the PRC laws, rules, regulations, regulatory authorities, and any PRC entities or citizens under such rules, laws and regulations and other legal or tax matters, excludes, Taiwan, the Hong Kong Special Administrative Region and the Macau Special Administrative Region;

“**Ordinary shares**” refer to our ordinary shares, par value US\$0.0001 per share;

“**RMB**” and “**Renminbi**” refer to the legal currency of China;

“**HKEx**” refers to The Stock Exchange of Hong Kong Limited;

“**HK\$**” refers to the legal currency of Hong Kong;

“**HKSCC**” refers to Hong Kong Securities Clearing Company Limited;

“**Hong Kong Listing Rules**” refer to the Rules Governing the Listing of Securities on HKEx, as amended, supplemented, or otherwise modified from time to time;

“**IFRS**” means the International Financial Reporting Standards, as issued by the IASB;

“**Innovent**” refers to Innovent Biologics (Suzhou) Co., Ltd., a company with limited liability established under the laws of the PRC;

“**Nasdaq**” means Nasdaq Global Market;

“**RSU**” means restricted share units;

“**SEC**” means the U.S. Securities and Exchange Commission;

“**SFC**” refers to the Securities and Futures Commission of Hong Kong; and

“**Takeda**” refers to Takeda Pharmaceuticals International AG; and

“**US\$**,” “**U.S. dollars**,” “**dollars**” and “**\$**” means United States dollars, the legal currency of the United States.

“**U.S. GAAP**” means United States generally accepted accounting principles.

INDUSTRY AND MARKET DATA

This Annual Report on Form 20-F includes industry, market and competitive position data that have been derived from publicly available information, industry publications and other third-party sources, as well as from our own internal data and estimates. Certain information and data, including statistics, estimates and projections about market size and future growth, included in this Annual Report on Form 20-F have been derived from an industry report commissioned by use and independently prepared by Frost & Sullivan, or the F&S Report. Independent consultant reports, industry publications and other published sources generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. While we have compiled, extracted, and reproduced industry data from these sources, we have not independently verified the data. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements in this Annual Report on Form 20-F. These forecasts and forward-looking information are subject to uncertainty and risk due to a variety of factors, including those described under “*Item 3. Key Information—D. Risk Factors.*” These and other factors could cause results to differ materially from those expressed in any forecasts or estimates.

TRADEMARKS AND SERVICE MARKS

“Ascentage,” the Ascentage logo and other trademarks or service marks of Ascentage appearing in this Annual Report on Form 20-F are the property of Ascentage or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 20-F are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this Annual Report on Form 20-F are the property of their respective owners.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 20-F may be forward-looking statements, including statements that express our opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results of operations or financial condition. These forward-looking statements are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In some cases, these forward-looking statements can be identified by words or phrases such as “aim,” “anticipate,” “believe,” “continue,” “estimate,” “expect,” “intend,” “is likely to,” “may,” “plan,” “potential,” “will,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These forward-looking statements reflect our current views with respect to future events and are subject to risks and uncertainties, some of which are beyond our control, or other assumptions and important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- our expectations regarding sales, manufacturing and commercialization of Olverembatinib and Lisaftoclax in China;
- our expectations regarding the clinical development, regulatory approval and commercialization of Olverembatinib and Lisaftoclax outside of China and of our other proprietary product candidates, including trial initiation, patient enrollment, trial completion, data announcements, regulatory filings, and timing thereof;
- our expectations regarding the potential advantages of our products and product candidates over existing therapies or therapies currently in development and expectations regarding the status of current therapies being used or being developed that are or may be competitive to our product candidates and potential changes to standard of care, and their comparative efficacy, safety, pharmacokinetics, or PK, pharmacodynamics, or PD, bioavailability and other characteristics;
- our expectations with regard to our ability to create, identify, nominate, select, research and develop additional product candidates and to submit investigational new drug application, or INDs, and/or Clinical Trial Applications, or CTAs, for our pre-clinical product candidates and timing thereof;
- our expectations regarding the potential advantages of our proprietary technologies over existing technology platforms, including drugs and therapies currently in development, and the prospects for our ongoing and future technology collaborations;
- developments and projections relating to our competitors and our industry, including competing therapies and technologies;
- our plans to expand our technology platform and the potential benefits of such platform;
- our expectations with regard to the willingness and ability of our current and future partners and collaborators to pursue the development, approval and commercialization of our products and product candidates;
- our and our partners’ product discovery, development and commercialization plans with respect to our products and product candidates and proprietary technologies;

- our potential to enter into new collaborations, including research and similar collaborations with research institutions and hospitals;
- our and our partners and collaborators' ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials and commercialize products that are approved;
- our expectations around the potential initiation, timing and success of clinical trials initiated by third parties, including IIT, of therapies including our products and product candidates;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals for our products and product candidates;
- our ability to identify, and to negotiate contracts with, suitable contract manufacturing organizations, or CMOs, contract research organizations, or CROs, and the ability of such CMOs and CROs to manufacture sufficient quantities of our products and product candidates for clinical trials or commercialization in compliance with current good manufacturing practices, or cGMPs;
- the commercialization and market acceptance of our products and product candidates;
- our plans to continue to build our commercialization capabilities and to commercialize and market Olverembatinib, Lisaftoclax or other proprietary product candidates that may be approved;
- the pricing of and reimbursement for our approved products in different markets;
- the implementation of our business model and strategic plans for our business, products, product candidates and technologies;
- our and our partners' ability to operate our businesses without infringing the intellectual property rights and proprietary technology of third parties;
- the scope of protection we and our partners are able to establish and maintain for intellectual property rights covering our products, product candidates and technologies;
- our analysis of potential patent infringement claims and our rights with respect to such claims, and expectations around patent coverage and effectiveness of such coverage for competitive products and product candidates;
- our receipt of future milestone payments, royalties and other payments from our partners, licensors and other collaborators and the expected timing of such payments;
- the impact of regulatory developments, legislative actions and political conditions in the United States, China, Hong Kong and other jurisdictions, including trade policies and tariffs that may apply to products that we purchase or sell, or judicial decisions overturning or establishing new legal precedents;
- our ability to operate in compliance with applicable laws which are complex and have different jurisdictional requirements;

- our ability to effectively manage our anticipated growth;
- our ability to attract and retain suitably qualified employees and key personnel, particularly for our commercialization efforts;
- our expectations around increase of headcounts and operations in key geographic areas;
- the timing, receipt of and terms and conditions of any required approvals, licenses or permits and the failure to renew, or the revocation of, any such approvals, licenses or permits;
- our estimates regarding future expenses, capital requirements and needs for additional financing;
- our expectation that the use of proceeds from our public and private financings and the period over which such proceeds, together with our available cash, will be sufficient to meet our operating needs; and
- our future financial performance.

You should refer to the section of this Annual Report on Form 20-F titled “*Item 3. Key Information—D. Risk Factors*” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, you should not rely on these forward-looking statements as predictions of future events.

The forward-looking statements contained in this Annual Report on Form 20-F are based on our current expectations and beliefs concerning future developments and their potential effects on us and speak only as of the date of this Annual Report on Form 20-F.

We will not, and do not, undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. You should therefore not rely on these forward-looking statements as representing our current expectations and beliefs as of any date subsequent to the date of this Annual Report on Form 20-F.

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

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

Our business faces significant risks and uncertainties. We are a Cayman Islands exempted company that conducts operations in multiple countries, primarily through our subsidiaries, with substantive business operations in China and in the United States. Under this holding company structure, investors in our ADSs hold equity interests in the Cayman Islands exempted company obtaining indirect ownership interests in our operating companies, including the PRC operating companies. This holding company structure involves certain risks to investors of our ADSs and ordinary shares. You should carefully consider all of the information set forth in this Annual Report on Form 20-F and in the other documents we file with or furnish to the SEC, including the following risk factors, before deciding to invest in or to maintain an investment in our securities. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks, any of which could have an adverse effect on the trading price of our securities. Additional risks not presently known to us or that we currently deem immaterial may also impair our business, financial condition and results of operations. In any such case, the market price of the ADSs could decline significantly, and you may lose all or part of your investment.

Below please find a summary of the principal risks we face, organized under relevant headings.

Risks related to our financial position and need for additional capital

- We have incurred significant net losses in the past, and we intend to continue to invest substantially in our business. As a result, we may not be able to achieve or sustain profitability in the future despite the commercialization of Olverembatinib and Lisaftoclax in China.
- We will need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates, including Olverembatinib and Lisaftoclax.
- Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our current or future products and our drug candidates, including Olverembatinib and Lisaftoclax.
- Our credit facility may not be available to us at all or on the same terms as it has in the past.
- We have a limited history of generating revenues on which to evaluate our potential for future success and as a result it is difficult to evaluate our current business and predict our future performance.

Risks related to clinical development

- Outside of China, we have not obtained any marketing authorization for any of our drug candidates. We depend substantially on the success of Olverembatinib, Lisoftoclax and our other drug candidates, several of which are in clinical development. Clinical development of drug candidates is inherently uncertain.
- If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or FDA, NMPA or other comparable regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of Olverembatinib and Lisoftoclax in the United States or elsewhere or the development and commercialization of our other drug candidates.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.
- Many of our drug candidates are being tested or used by patients who are critically ill, who may be unfit for certain medical interventions or for whom there are no other treatments or options, which can result in heightened risk of adverse events, including death.
- Interim, initial, top-line and preliminary data from our clinical trials that we announce or publish from time to time may materially change as more patient data become available and are subject to audit and verification procedures. We may also selectively report data to explore certain trends that are interesting, but you may not agree with our assessment as to what might be material or appropriate.
- We may not be successful in our efforts to identify or discover additional drug candidates. Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain drug candidates; these decisions may prove to be wrong and may adversely affect our business.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Risks related to obtaining regulatory approval

- The regulatory approval processes of the FDA, NMPA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.
- The FDA, NMPA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.
- If we are unable to obtain NMPA approval for our drug candidates to be eligible for an expedited registration pathway as Category 1 drug candidates, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive such Category 1 designation, it may not lead to a faster development, review or approval process.
- Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration 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.

Risks related to commercialization

- We are substantially dependent on the commercial success of Olverembatinib and Lisoftoclax. If we are unable to maintain or increase sales of Olverembatinib and Lisoftoclax, our ability to generate revenue and our financial condition will be adversely affected.

- If we are not able to obtain, or experience delays in obtaining, required regulatory approvals for our drug candidates (including Olverembatinib and Lisoftoclax outside of China), we will not be able to commercialize our drug candidates in the markets that we desire, and our ability to generate revenue will be materially impaired.
- We have and may continue to license commercialization or other rights and pursue other forms of collaboration worldwide, which can expose us to additional risks of conducting business in additional international markets.
- We have limited commercialization experience, and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our other products that receive regulatory approval on our own or together with collaborators.

Risks related to our intellectual property

- If we are unable to protect and defend our proprietary technology or obtain and maintain patent protection for our drug candidates, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

Risks related to our reliance on third parties

- We rely on third parties to manufacture a portion of our drug candidate supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our drug candidates, including Olverembatinib and Lisoftoclax. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.
- We have entered into collaborations and other relationships with leading biotechnology companies and research institutions and may form or seek other collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.
- We rely on third parties to conduct our preclinical studies and clinical trials and we must work effectively with collaborators to develop our drug candidates. In many cases, our drug candidates, including Olverembatinib and Lisoftoclax, are studied in third-party studies, including in investigator-initiated trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or fail to design, execute, and complete appropriate and timely studies of our drug candidates, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

Risks related to our industry, business and operations

- If our manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.
- We have significantly increased our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.
- Any failure to comply with applicable regulations and industry standards or obtain or maintain various licenses and permits could harm our reputation and our business, results of operations and prospects.
- The tension in international trade, rising political tension and increasing geopolitical risks, particularly between the United States and China, pose significant challenges that may adversely impact our business, results of operations and financial condition.

Risks related to doing business in the PRC

- We are subject to continued approval, filing and other requirements of applicable U.S. securities laws and Nasdaq listing rules as a U.S. public company, and may be subject to further approval, filing or other requirements with PRC governmental authorities in connection with future capital-raising activities.
- Recent greater oversight by the Cyberspace Administration of China, or CAC, over data security, particularly for companies seeking to list on a foreign exchange, could significantly limit or completely hinder our ability in capital raising activities and materially and adversely affect our business and the value of your investment.

- If the Public Company Accounting Oversight Board, or PCAOB, is unable to inspect or investigate completely our auditors located in China because of a position taken by a foreign authority and the SEC identifies the Company as a Commission-Identified Issuer under the Holding Foreign Companies Accountable Act for two consecutive years, our ADSs will be delisted from Nasdaq and our ordinary shares and ADSs will be prohibited from trading on a national securities exchange or in the over-the-counter market in the U.S. under the Holding Foreign Companies Accountable Act. The delisting of our ADSs, or the threat of their being delisted, and a prohibition from trading, may materially and adversely affect the value of our ordinary shares.
- Existing regulation and future legislative actions in both the U.S. and China may restrict our ability to transfer our scientific data abroad.

Risks related to our ordinary shares and our ADSs

- The dual listing of our ordinary shares and ADSs may adversely affect the liquidity and value of our ADSs and ordinary shares.
- The trading prices of our ADSs have been and are likely to be volatile, which could result in substantial losses to you.
- If we fail to maintain an effective system of internal controls over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence and the market price of our ADSs may be materially and adversely affected.

Risks related to our financial position and need for additional capital

We have incurred significant net losses in the past, and we intend to continue to invest substantially in our business. As a result, we may not be able to achieve or sustain profitability in the future despite the commercialization of Olverembatinib and Lisoftoclax in China.

We incurred a net loss of RMB1,243.0 million (US\$177.7 million), RMB405.7 million and RMB925.7 million for the years ended December 31, 2025, 2024 and 2023, respectively. As of December 31, 2025, we had accumulated losses of RMB7,013.3 million (US\$1,002.9 million). Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have devoted significant financial resources to research and development, including our nonclinical development activities and clinical trials. We continue to incur significant development and other expenses related to our ongoing operations.

Although we have commercialized Olverembatinib and Lisoftoclax in China, we have several other drug candidates in clinical and preclinical development. In addition, we expect to incur significant expenses related to obtaining regulatory approvals for Olverembatinib and Lisoftoclax in additional markets, including the United States. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs, selling and distribution expenses associated with commercialization of Olverembatinib and Lisoftoclax in China and general and administrative expenses associated with our operations.

We expect to continue to incur substantial and increasing losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates (including Olverembatinib and Lisoftoclax outside of China), and commercialize such drug candidates, if approved. Typically, it takes many years to develop one new drug candidate from the time it is discovered to when it is available for treating patients. 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, in part, on the rate of future growth of our expenses, our ability to generate revenues and the timing and amount of milestones and other required payments to third parties in connection with our potential future arrangements with third parties. If any of our drug candidates (including Olverembatinib and Lisoftoclax) fail in clinical trials or do not gain regulatory approval for the indications we seek or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable may decrease the value of our Company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our research and development platform and our ongoing and planned clinical trials for our drug candidates, including for Olverembatinib and Lisoftoclax. If we obtain regulatory approval for Olverembatinib and Lisoftoclax and our other drug candidates in the United States or other jurisdictions, we expect to incur increased sales and marketing and manufacturing and other expenses as we prepare to commercialize the approved drugs. In addition, we will continue to incur additional costs associated with operating as a U.S. and Hong Kong-listed public company.

As a result, if we fail to increase our revenues to offset the increases in our operating expenses, we expect to continue to incur operating losses for the foreseeable future. Our prior losses and expected future losses have had and will continue to have a material adverse effect on our financial condition and results of operations.

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

We have funded our operations primarily through equity financing. We have also received government subsidies that consist of funds from local governments as compensation for research activities and clinical trials, for which there are no outstanding obligations, as well as tax credits in China and Australia. Such government subsidies were mainly R&D-related subsidies received from the provincial and municipal governments of Suzhou and Guangzhou and the local taxation office in Australia for the years ended December 31, 2025 and 2024. Other than Olverembatinib and Lisoftoclax, which has been commercialized in China, we do not have any products approved for commercial sale in any other jurisdiction. During the years ended December 31, 2025, 2024 and 2023, we recognized RMB574.1 million (US\$82.1million), RMB980.7 million and RMB222.0 million, respectively, in revenue from the sales of pharmaceutical products, commercialization rights income from our agreement with Innovent, intellectual property income from our agreement with Takeda and management fee income. Our other drug candidates (including Olverembatinib and Lisoftoclax outside of China) will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any product sales revenue. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates and launching and commercializing any drug candidates for which we receive regulatory approval (including Olverembatinib and Lisoftoclax), including by building and expanding our own commercial organizations to address certain markets.

As of December 31, 2025 we had RMB2,470.1 million (US\$353.2 million) in cash and bank balances. We believe that our existing cash and bank balances and our loan facility, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 20-F but may not be sufficient for us to fund any of our drug candidates through regulatory approval, which may last several years. We will need to obtain substantial financing to fund our future operations, including completing the development and commercialization of our drug candidates, including Olverembatinib and Lisoftoclax in the United States. Even if one or more of the drug candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing, and distribution activities. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the NMPA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any drug candidate we develop. We are not permitted to market or promote Olverembatinib and Lisoftoclax in the United States or other jurisdictions outside of the PRC, or any other drug candidate, before we receive marketing approval from the FDA, NMPA or other regulatory agencies. Moreover, we expect to increase our headcounts to support our expansion and our fixed expenses such as rent, interest expense and other contractual commitments are also expected to increase in the future.

Our cash and financial resources to support our operations involve risks and uncertainties, including the factors discussed elsewhere in this “Risk Factors” section. We could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA, NMPA and comparable regulatory authorities, including the potential that the FDA, NMPA or comparable regulatory authorities may require that we perform more studies than those that we currently expect;
- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities;
- the number and characteristics of drug candidates that we may develop (including as a combination therapy) and the requirements of any future acquisitions, in-licenses or collaborations;
- the amount of sales and other revenues from Olverembatinib, Lisoftoclax and other drug candidates that we may commercialize, if any, including the selling prices for such potential products, if and when approved, and the availability of adequate third-party reimbursement;
- the amount and timing of the milestone, royalty and/or other payments we receive under arrangements with our licensees, partners and collaborators, such as our collaboration and licensing agreement with Innovent, or are or may be required to pay under our current and future collaborations, licensing and other similar arrangements, and the terms of those arrangements;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our current and future products, including the cost and timing of expanding our marketing and sales capabilities;
- the costs of operating as a public company in both Hong Kong and the United States; and
- the time and cost necessary to respond to technological and market developments.

Until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. General market conditions or the market price of our ordinary shares or ADSs may not support capital raising transactions such as an additional public or private offering of the ADSs or other securities.

The global economy, including credit and financial markets, has experienced volatility and disruptions recently. While the potential economic impacts of the current U.S. administration, geopolitical conflicts in Russia and Ukraine, Iran and the Middle East and in South America, and tensions in U.S.-China relations are difficult to assess or predict, these conditions have resulted in, and may continue to result in, volatility and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. In addition, any public health emergencies may also cause extreme volatility and disruptions in the capital and credit markets. Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on favorable terms, if at all. The Federal Reserve raised interest rates multiple times in the past in response to concerns about inflation, and it may raise them again or determine not to continue to lower them in a timely manner. Higher interest rates, coupled with reduced government spending and volatility in financial markets, and recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures, may increase economic uncertainty and affect consumer spending.

If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Therefore, our inability to obtain additional funding when we need it could seriously harm our business.

Raising additional capital will cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our current or future products and our drug candidates, including Olverembatinib and Lisaftoclax.

We may seek additional funding through a combination of equity offerings, government or private party grants, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of the ADSs. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur debt, issue additional equity, declare dividends, acquire or license intellectual property rights, make capital expenditures and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of the ADSs to decline. In the event that we enter into collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties in order to raise capital, we may be required to grant licenses on terms that may not be favorable to us or relinquish valuable rights to our current or future revenue streams or rights to Olverembatinib, Lisaftoclax or our other drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms. We could also potentially have to share or relinquish certain rights to our platform or other assets.

Our credit facility may not be available to us at all or on the same terms as it has in the past.

Our credit facility contains restrictive covenants that primarily limit our ability to transfer or dispose of assets, merge with other companies or consummate certain changes of control, acquire other companies, conduct material investments or related party transactions, issue bonds, pay dividends, incur additional indebtedness and liens and enter into new businesses. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate the credit facility, which may limit our operating flexibility. In addition, to secure our credit facilities, we may grant security interests from time to time. As of December 31, 2025, bank loans amounting to RMB600.2 million (US\$85.8 million) were secured by the pledge of our buildings with a net carrying amount of RMB677.0 million (US\$96.8 million) and right-of-use assets with a net carrying amount of RMB25.3 million (US\$3.6 million). Such loans were also guaranteed by two of our subsidiaries. Any failure to satisfy our obligations under these bank loans could lead to foreclosure of the assets that secure these borrowings, disruption to business operations and payment obligations of our relevant subsidiaries, which could materially and adversely affect our business, results of operations and financial condition. There is no guarantee that we will be able to make scheduled payments for the principal and interest on any such loans or meet the restrictive covenants on our credit facility. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance any such loans. As a result, we would be in default of such loans, and the relevant counterparty could elect to declare the borrowings, together with accrued and unpaid interest and other fees, immediately due and payable and proceed against security interests under the loans, if any. If the borrowings were to be accelerated, our business and liquidity could nevertheless be subject to adverse effects.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2025, Ascentage Pharma Group Inc., our U.S. subsidiary located in Rockville, Maryland, had federal and state net operating loss carryforwards, or NOLs, of US\$231.2 million and US\$18.4 million, respectively, due to prior period losses. The Tax Cuts and Jobs Act of 2017, or the TCJA, allows for federal NOLs incurred in tax years beginning after December 31, 2017, to be carried forward indefinitely. The deductibility of federal NOLs is limited to 80% of the current year's taxable income. However, NOLs generated prior to January 1, 2018, will still have a 20-year carryforward period, but are not subject to the 80% limitation. Furthermore, our ability to use NOLs is conditioned on Ascentage Pharma Group Inc. achieving and maintaining profitability in the future and generating U.S. federal taxable income. Since we do not know whether or when Ascentage Pharma Group Inc. will generate the U.S. federal taxable income necessary to use its remaining NOLs, its NOLs generated prior to January 1, 2018, could expire unused.

We have a limited history of generating revenues on which to evaluate our potential for future success and as a result it is difficult to evaluate our current business and predict our future performance.

We were founded in 2009 and did not generate any revenue from product sales until 2021. While we have commercialized Olverembatinib and Lisoftoclax in China, we have not received regulatory approval for Olverembatinib and Lisoftoclax in the United States or any other market, and we have no other products approved for commercial sale in any market.

Consequently, any predictions you or we make about our future success or viability are subject to significant uncertainty and may not be as accurate as they could be if we had a longer operating history. We are focused on discovering, developing and commercializing therapies for hematological malignancies. Our limited operating history as a revenue generating company, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and predict our future performance. We will encounter risks and difficulties frequently experienced by clinical-stage companies in rapidly evolving fields. Additionally, as we pursue new indications and enter new markets, we may also encounter additional and new challenges and risks, including those associated with further expanding our global footprint and operations. If we do not address these risks and difficulties successfully, our business will suffer.

We currently have several drug candidates in clinical development, and their risk of failure is high. We are unable to predict if these drug candidates or any of our other drug candidates that advance into clinical trials will prove safe or effective in humans or will obtain marketing approval. Because of the uncertainties and risks associated with clinical development activities, we face a significant risk of business failure. We can provide investors with no assurance that we will recover all or any portion of our capital investment in the clinical development of our drug candidates. If we are unsuccessful in addressing these risks, our business will most likely fail, and our investors could lose all or substantially all of their investments.

Risks related to clinical development

Outside of China, we have not obtained any marketing authorization for any of our drug candidates. We depend substantially on the success of Olverembatinib, Lisoftoclax and our other drug candidates, several of which are in clinical development. Clinical development of drug candidates is inherently uncertain.

To date, we have obtained regulatory approval in China for (a) Olverembatinib for the treatment of adult patients with chronic myeloid leukemia in chronic phase, or CML-CP, or chronic myeloid leukemia in accelerated phase, or CML-AP, with the T315I mutation and adult patients with CML-CP that is resistant or intolerant to first- and second- generation tyrosine kinase inhibitors, or TKIs, from NMPA and (b) Lisoftoclax for the treatment of adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma, or CLL/SLL, who have previously received at least one systemic therapy including Bruton's tyrosine kinase, or BTK, inhibitors. Outside of China, we have not obtained marketing approval for any drug candidates conducted sales and marketing activities necessary for successful commercialization of any approved products.

We may fail to or be unable to design and execute clinical trials to support marketing approval of Olverembatinib or Lisoftoclax outside of China, or any of our other drug candidates. We cannot be certain that our current or planned clinical trials or any other future clinical trials will be completed on time or be successful. We cannot guarantee that the FDA or foreign regulatory authorities will agree with our study design, protocol or protocol amendments, or statistical plan, or that they will interpret clinical trial results as we do, and more clinical trials could be required before we are able to submit applications seeking approval of our drug candidates. To the extent that the results of the clinical trials are not satisfactory to the FDA or the applicable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our drug candidates, including potential confirmatory or Phase 3 registrational trials. Even if regulatory approval is secured for any of our drug candidates, the terms of such approval may limit the scope and use of our drug candidate, which may also limit its commercial potential.

Our business and the ability to achieve and maintain profitability will depend on the continued commercialization of Olverembatinib and Lisaftoclax and the successful development, regulatory approval and commercialization of our drug candidates in key global markets, including Olverembatinib and Lisaftoclax in the United States and other jurisdictions. We have invested a significant portion of our efforts and financial resources in expanding the approved indications for Olverembatinib and Lisaftoclax in China, extending regulatory approval of Olverembatinib and Lisaftoclax to other countries, and the continuing clinical development of our other drug candidates in clinical trials around the world. The successful clinical development of Olverembatinib and Lisaftoclax in the United States and other jurisdictions and our other drug candidates will depend on several factors, including:

- successful and timely completion of nonclinical and clinical development of our drug candidates and any future drug candidates, as well as the associated costs, including any unforeseen costs;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development, both in the United States and internationally, of our drug candidates and any future drug candidates;
- timely submission of application for and receipt of marketing approvals from applicable regulatory authorities for any drug candidates for which we successfully complete clinical development;
- receipt of regulatory approvals from the FDA, NMPA and other comparable regulatory authorities for our drug candidates;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our drug candidates both in China and in countries outside of China, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for drug candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether inhouse or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our drug candidates;
- commercial acceptance of our drug candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new drug candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, in China, the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, test, manufacture or commercialize our drug candidates, including any rights relating to third- party drug products and therapies used in combination therapies with our drug candidates;
- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for drug candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to successfully complete the clinical development of our drug candidates or commercialize Olverembatinib and Lisaftoclax in accordance with the NMPA approval in China, which would materially harm our business and our ability to generate sufficient revenues and cash flows to continue our operations.

We may also experience delays in developing an approvable, sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our drug candidates, including Olverembatinib and Lisaftoclax in the United States or in other jurisdictions outside of China, on a timely or profitable basis, if at all. If we need to transfer a portion of our manufacturing process to commercial partners, we are aware of only a limited number of companies on a worldwide basis who operate manufacturing facilities in which our drug candidates can be manufactured under cGMP regulations. It would take a substantial period of time for a contract facility that has not been producing small-molecule therapeutics to begin producing such under cGMP. We cannot be certain that we will be able to contract with any of these companies on acceptable terms, if at all. New manufacturers would also need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such ingredients.

Changes in the manufacturing process or facilities will require further comparability analysis and approval by the FDA and other relevant regulatory authorities before implementation, which could delay our clinical trials and drug candidate development, and could require additional clinical trials, including bridging studies and potential confirmatory or Phase 3 registrational trials, to demonstrate consistent and continued safety and efficacy.

We have not submitted any new drug application, or NDA, to the FDA for any drug candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the drug candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the drug product. We cannot be certain that our current or future drug candidates will be successful in clinical trials. Further, even if they are successful in clinical trials, our drug candidates or any future drug candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future drug candidates beyond our NMPA approval for Olverembatinib and Lisoftoclax, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a drug candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products and therapies, whether there is sufficient third-party reimbursement and adoption by physicians.

In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainty in the industry, and disrupt the FDA's normal operations. Further, changes in the leadership, policies, and funding of FDA and other federal agencies under the current U.S. administration can have a material impact on FDA's operations as well as our manufacturing, clinical and commercial development plans and timelines.

In February 2025, an executive order was signed asserting greater authority over all federal agencies, including those established by Congress as independent from direct presidential control. The executive order may lead to delays, if not cancellations, of pending and proposed regulations at federal agencies and introduces uncertainty as it subjects all significant regulatory actions by the agencies to the President's supervision and control. We cannot predict the impact that such executive order, any future executive orders or legislation implementing executive orders may have on our business or our results of operations.

Aside from the NMPA approvals that we have obtained to date for Olverembatinib and Lisoftoclax, if clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, NMPA or other comparable regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to obtain approval and complete, the commercialization of Olverembatinib and Lisoftoclax in the United States or the development and commercialization of our other drug candidates.

Before obtaining regulatory approval for the sale of Olverembatinib and Lisoftoclax in the United States or in other jurisdictions outside of China or regulatory approval for the sale of other drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval of or commercialize our drug candidates, including, but not limited to:

- regulators, or institutional review boards, or IRBs, data safety monitoring boards, or DSMBs, or ethics committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates, whether as a monotherapy or a combination therapy, may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate, or patients may drop out at a higher rate than we anticipate;
- our third-party contractors, including clinical sites and investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including, but not limited to, a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;
- regulators, IRBs, DSMBs or ECs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; and
- our drug candidates, drugs that may be used in combination with our drug candidates or drug candidates in the same class as our drug candidates may cause adverse effects, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Delays in testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be redesigned or will be completed on schedule, or at all.

Additionally, as some of our drug candidates represent a novel approach to cancer treatment, they carry inherent development risks that could result in delays in clinical development, heightened regulatory scrutiny, or delays in our ability to achieve regulatory approval. We may be required to further develop or modify the protocols related to our drug candidates to demonstrate safety or efficacy, which may delay clinical programs, regulatory approval or commercialization of our drug candidates, including Olverembatinib and Lisoftoclax in the United States and other jurisdictions outside of China, if approved. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than enroll patients in any current or future clinical trial.

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

Our product candidates (including Olverembatinib and Lisoftoclax) may cause or be associated with significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials or in post-approval studies when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or result in subsequent regulatory limitations, including black box warnings. Treatment-related side effects or other adverse events, whether treatment related or not, that may occur while a patient is on the treatment could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability or other claims. Any of these occurrences may also prevent us from achieving or maintaining market acceptance of the affected product and may harm our business, financial condition and prospects significantly.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, we may be unable to enroll a sufficient number of patients on a timely basis, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, NMPA, other comparable regulatory authorities or IRBs, DSMBs or ECs may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Additionally, if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug;
- regulatory authorities may require additional warnings on the label or narrow the proposed indication for our drug candidate;
- we may be required to develop a Risk Evaluation and Mitigation Strategy, or REMS, for the drug or, if a REMS is already in place, to incorporate additional requirements under the REMS, 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 sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, results of operations and prospects.

Further, toxicities associated with approved drugs that have not been seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the drug product or the withdrawal of the drug product from the market. We cannot predict whether Olverembatinib and Lisafoclax or our other drug candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

Many of our drug candidates are being tested or used by patients who are critically ill, who may be unfit for certain medical interventions or for whom there are no other treatments or options, which can result in heightened risk of adverse events, including death.

Our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. Patients treated with our product candidates may also be undergoing other treatments, including surgery, radiation, chemotherapy and other regimens, any of which can individually or together cause side effects or adverse events, including illness, progression of disease and death, that may not be related to our product candidate but may still impact the success of our clinical trials. Many of our drug candidates are being tested in or used by patients after having failed or developed intolerance or resistance to other therapies or critically ill individuals who are unfit for certain medical interventions or for whom there are no other treatments or options available. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses or weakened condition. Therefore, it is expected that some of the patients enrolled in our clinical trials or who otherwise receive any approved drugs could die or experience major clinical events either during or after the course of our clinical trials or receiving treatment, which has occurred in the past.

Interim, initial, top-line and preliminary data from our clinical trials that we announce or publish from time to time may materially change as more patient data become available and are subject to audit and verification procedures. We may also selectively report data to explore certain trends that are interesting, but you may not agree with our assessment as to what might be material or appropriate.

From time to time, we may publicly disclose preliminary or top-line 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 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 data should be viewed with caution until the final data are available.

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. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our ADSs representing our ordinary shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, 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 drug and our Company in general. 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 you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. Hematological malignancies and other indications for which we develop drug products are inherently complex and heterogeneous, and the existence of certain mutations and biomarkers can impact the response rates and risk of adverse events. The pathways that we target can also implicate different diseases and indications and result in clinical trials where we enroll patients with different diseases. Additionally, these diseases are often treated with multiple lines of therapies resulting in patient populations with different treatment history and resistance or intolerance to certain existing drugs or therapies.

Therefore, from time to time, we may also selectively report data for a certain subpopulation of patients that received the study drug in a particular study, such as patients who received a particular dose or patients who have a specific indication or have specific characteristics such as a specified mutation, intolerance to certain treatments or other high risk indicators, or combine similar patients across studies. There is no guarantee that these data cuts will be representative of the indications or subpopulations for which we pursue approval, and there is risk that such data, being either a smaller subset of patients treated or an amalgamation across multiple studies, and conclusions and interpretations may not predict future results. If the interim, top-line or other 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, financial condition and results of operations.

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

Preclinical studies and clinical testing are expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the preclinical or clinical trial process. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, patient adherence to the dosing regimen, and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials.

Notwithstanding any potential promising results in earlier studies and trials for any drug candidate, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, in vitro or other laboratory testing, may not be predictive of the results of outcomes in human clinical trials. For example, our drug candidates may demonstrate different chemical, biological, and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Drug candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of the relevant drug candidate as well as other drug candidates employing the same technology, which could have a significant impact on our product pipeline and future growth prospects. Even if we are able to initiate and complete the necessary clinical trials, the results may not be sufficient to obtain regulatory approval for our drug candidates.

Data obtained from preclinical studies and clinical trials are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. At each phase of clinical development, we must ask for the appropriate authorization from the relevant authorities in applicable jurisdictions before we can conduct clinical trials and then present the results of the clinical trials to these authorities. The authorities may refuse to provide the authorizations necessary for clinical trials or have additional requirements (for example, relating to study protocols, patient characteristics, treatment durations, post-treatment follow-up, certain differences in interpreting results between local regulatory agencies), and in some cases may require additional studies. Any refusal or decision by health authorities to require additional trials or examinations would be likely to result in the discontinuation or delay of the development of the products concerned.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs, DSMBs or ECs of the institutions in which such clinical trials are being conducted, by a DSMB for such clinical trial or by the FDA or comparable foreign regulatory authorities. Clinical trials can be delayed or terminated or fail to meet endpoints for a variety of reasons, including, but not limited to, delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our clinical development strategy or statistical plan;
- changes in governmental regulations or administrative actions;
- delays in our ability to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB, DSMB and/or EC approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial on a timely basis;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- protocol deviations or non-compliance with Good Clinical Practice, or GCP, requirements, or other data integrity reasons, that cause us or the FDA or other regulatory authorities to exclude data from non-compliant sites or investigators, which may cause the trial to be underpowered to meet the endpoints;
- delays by us or our CROs in qualifying or analyzing patient data at the completion of clinical trials;
- failure to demonstrate a benefit from using a drug candidate;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient supply of drug candidates for use in nonclinical studies or clinical trials from third-party suppliers.

Further, conducting clinical trials in foreign countries, as we intend to do for our drug candidates, presents additional risks that may delay completion of our clinical trials. These risks include, but are not limited to, the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, 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, particularly as we move towards the commercial stage of our drug candidates, we may be required to report some of these relationships to the FDA, certain national registers or other applicable agencies and 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 experience delays in the completion of, or termination of, any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product revenues from any of these drug candidates will be delayed.

Moreover, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

If the results of our current and future clinical trials are inconclusive with respect to the efficacy of our drug candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our drug candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our drug candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes in the way the drug candidate is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the drug product or impose restrictions on its distribution in the form of a modified REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be subject to litigation, investigations, proceedings, or other actions; or
- experience damage to our reputation.

An absence of or delay in therapeutic response could also result in the delay or even discontinuation of the development of our drug candidates. We cannot guarantee that the development of our drug candidates will ultimately be successful, especially within time frames compatible with our financial resources or market needs. Any failure or delay in the development of these products would have a material adverse effect on our business, income, financial condition and outlook.

Many of our drug candidates are in early stages of clinical trials.

Olverembatinib and Lisoftoclax are our only drug candidates that have received regulatory approval in any jurisdiction. Each of Olverembatinib and Lisoftoclax are also in Phase 3 registrational trials for other indications, and we have ongoing clinical trials for Alrizomadlin, Pelcitoclax, APG-5918, APG-2449, APG-3288, and other product candidates. Regulatory approval generally requires the completion of a Phase 3 clinical trial to test the safety and efficacy of the drug candidate on a large sample of patients unless an expedited program or pathway is granted by relevant regulatory authorities. The timeline between a Phase 1 clinical trial and a Phase 3 clinical trial and subsequent filing of an NDA or foreign equivalent can take several years. We will need to commit substantial time and additional resources to conduct further nonclinical studies and clinical trials before we can submit an NDA or foreign equivalent with respect to any of our drug candidates. We cannot predict with any certainty if or when we might submit an NDA or foreign equivalent for regulatory approval for any of our drug candidates.

We may not be successful in our efforts to identify or discover additional drug candidates. Due to our limited resources and access to capital, we must, and have in the past decided to prioritize development of certain drug candidates; these decisions may prove to be wrong and may adversely affect our business.

Our future results of operations are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize drug candidates beyond those we currently have in clinical and nonclinical development. A drug candidate can unexpectedly fail at any stage of nonclinical and clinical development. The historical failure rate for drug candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care, and other unpredictable variables. The results from nonclinical testing or early clinical trials of a drug candidate may not be predictive of the results that will be obtained in later stage clinical trials of the drug candidate. If we fail to identify potential drug candidates, our business could be materially harmed. The success of other future drug candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;

- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the drug candidate for use in clinical trials; and
- adverse events in the clinical trials.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Even if we identify suitable new drug candidates, such drug candidates may not achieve proof of concept in a cost-effective manner or at all. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including, but not limited to:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, 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. Decision-making about which drug candidates or other indications to prioritize involves inherent uncertainty. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Accordingly, there can be no assurance that we will be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

Our clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors, or they may fail to meet the enrollment criteria due to having been on certain treatments previously. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

We develop drug candidates in combination with other therapies, which exposes us to additional risks.

We develop drug candidates in combination with one or more other approved or unapproved therapies. Even if any drug candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our drug product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our drug candidates are replaced as the standard of care for the indications we choose for any of our drug candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own drug products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate drug candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any drug candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our drug product. In addition, unapproved therapies face the same risks described with respect to our drug candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our drug candidate we develop, we may be unable to obtain approval of or market such combination therapy.

Changes in methods of drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our 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 completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to commercialize our drug candidates, if approved, and generate revenue.

Risks related to obtaining regulatory approval

The regulatory approval processes of the FDA, NMPA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

Our drug candidates, including Olverembatinib and Lisaftoclax, and the activities associated with their development and commercialization, including their research, development, design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize and market any of our drug candidates, we must obtain marketing approval for the desired indication and patient population.

Obtaining approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the drug candidates involved. 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, which may cause delays in the approval or the decision not to approve an application. For example, if the FDA or other regulatory authority requires us to change our study protocol or design, our clinical trial plans may be delayed. Further, securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by the relevant regulatory authority. Regulatory authorities have broad authority in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other data. Even if we eventually complete clinical testing and receive marketing approval for our drug candidates, the FDA and other comparable foreign regulatory authorities may approve our drug candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the drug candidate's commercial potential. We have not submitted for, or obtained, marketing approval for any drug candidate outside of China, and it is possible that none of our drug candidates will ever obtain such regulatory approval. Further, development of our drug candidates or regulatory approval may be delayed for reasons beyond our control.

We have obtained NMPA approvals for Olverembatinib for the treatment of adult patients with CML-CP with the T315I mutations, CML-AP with the T315I mutations, and CML-CP resistant or intolerant to first and second-generation TKIs and for Lisoftoclax for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy including BTK inhibitors. We are authorized to market Olverembatinib and Lisoftoclax for these approved indications in China. However, in order to market in other regions such as the United States and other jurisdictions, we must obtain regulatory approvals or clearances in those jurisdictions. None of our other drug candidates have received marketing approval from any regulatory authority, other than Olverembatinib and Lisoftoclax in China as described above. It is possible that none of our existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

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

- such regulatory authority's 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 clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- data integrity issues related to our clinical trials;
- such regulatory authority's disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our drug candidates to support the submission and filing of a NDA or other submission to obtain regulatory approval;
- the FDA, NMPA or comparable regulatory authority's finding of deficiencies related to the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA, NMPA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that is not desirable for the successful commercialization of that drug candidate. In addition, if our drug candidate produces undesirable side effects or safety issues, the FDA may approve any of our drug candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings or a REMS. Regulatory authorities may not approve the price we intend to charge for drug products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate, or restrict distribution of our drug candidates and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates. Of the large number of drugs in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval processes as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our drug candidates, which would significantly harm our business, results of operations and prospects.

The FDA, NMPA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

The acceptance of study data by the FDA, NMPA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States or vice versa, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, NMPA or any applicable foreign regulatory authority does not accept such data, there is a risk 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.

Uncertainty in the regulatory framework could also result in disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may increase our development lead time to marketing authorization and commercialization of products in the United States and/or other jurisdictions and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

If we are unable to obtain NMPA approval for our drug candidates to be eligible for an expedited registration pathway as Category 1 drug candidates, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive such Category 1 designation, it may not lead to a faster development, review or approval process.

The NMPA categorizes domestically manufactured innovative drug applications as Category 1, provided such drug has a new and clearly defined structure, pharmacological property and apparent clinical value and has not been marketed anywhere in the world. Domestically developed and manufactured innovative drugs will be attributed to Category 1 for their clinical trial application, or CTA, and NDA applications. While some multinational pharmaceutical companies may file CTAs with the NMPA prior to approval of a drug in another country in order to take advantage of Category 1 classification, such drug will most likely be assigned to Category 5 for NDA approval purposes because, based on historical observations, multinational pharmaceutical companies will typically not prioritize applying for local manufacturing rights in China, hence subjecting the drug to the imported drug status. The imported drug registration pathway is more complex and is evolving. Imported drug registration applications in China may only be submitted after a drug has obtained an NDA approval and received the Certificate of Pharmaceutical Product granted by a major drug regulatory authority, such as the FDA. A Category 1 designation by the NMPA may not be granted for any of our drug candidates or may not lead to faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our drug candidates will receive regulatory approval. 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 more information, see “Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation.”

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.

Where appropriate, we plan to pursue approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration 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 post-marketing requirements or commitments, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our drug candidates. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act of 1938, or FDCA, and the FDA’s implementing regulations, 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 Food and Drug Omnibus Reform Act made several changes to the FDA’s authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

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 verify 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 such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such 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 NDA 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 under another expedited regulatory designation (e.g., breakthrough therapy designation), 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 regulatory approval.

Olverembatinib has been granted Fast Track designation from the FDA for the treatment of CML in patients with certain genetic markers who have failed to respond to treatments with existing TKIs. In the United States, Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the drug candidate and the specific indication for which it is being studied. If any of our drug candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

To the extent we obtain orphan drug designation, rare pediatric disease and/or Fast Track designation, we may not be able to maintain or take advantage of all the benefits associated with such designations for our drug candidates. Further, orphan drug exclusivity may not prevent the FDA, NMPA or other comparable foreign regulatory authorities from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the product for the indication can be recovered by sales of the product in the United States.

Generally, if a drug with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or NMPA from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States and 10 years in the European Union. The European Union exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or NMPA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

In particular, Olverembatinib was granted orphan drug designation by FDA for the treatment of CML, acute myeloid leukemia, or AML, acute lymphocytic leukemia, or ALL, and gastrointestinal stromal tumor, or GIST, and a Fast-Track Designation for the treatment of CML in patients with certain genetic markers who have failed to respond to treatments with existing TKIs. Lisoftoclax was granted orphan drug designation for the treatment of myelodysplastic syndrome. Such designations may not effectively protect the drug candidate from competition because different drugs can be approved for the same condition and the same drugs can be approved for a different condition but used off-label for any orphan indication we may obtain. Even after an orphan drug is approved, the FDA can subsequently approve a drug that is otherwise the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, Congress, in an amendment to the Orphan Drug Act in the Consolidated Appropriations Act of 2026 or CAA, clarified that orphan drug exclusivity applies to the FDA's same approved use or indication within a rare disease, rather than the entire rare disease or condition. The change abrogated the decision in *Catalyst v. Becerra* and aligns the statutory text with the FDA's longstanding interpretation. This change makes explicit that orphan drug exclusivity blocks approval of the same drug only for the same approved use or indication, not for all uses within the broader designated disease. The amendment also applied retroactively. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug candidate any advantage in the regulatory review or approval process or entitles the drug candidate to priority review.

Under the rare pediatric disease designation and priority review voucher, or PRV, program, a sponsor that receives an approval for a drug product for a rare pediatric disease may qualify for a voucher that can be redeemed to receive priority review for a different product. The sponsor may transfer or sell the voucher to another sponsor. FDA awards rare pediatric disease PRVs to sponsors of rare pediatric disease products that are approved and meet certain criteria. The PRV program was previously subject to a sunset period by which eligibility to receive a voucher was limited to products that received rare pediatric disease designation by December 20, 2024. However, as of February 3, 2026, the enactment of the CAA has allowed the program to resume and reauthorizes designations until September 30, 2029. To date, we have received rare pediatric disease designation for at least one of our drug candidates but not an approval, and changes to the rare pediatric disease program can impact our ability to realize the full benefits of the designation.

Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Regulatory approval may be substantially delayed or may not be obtained for our drug candidates (including Olverembatinib and Lisoftoclax outside of China) if regulatory authorities require additional time or studies to assess the safety and efficacy of our drug candidates.

If regulatory authorities require additional time or studies to assess the safety or efficacy of our drug candidates, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our drug candidates. Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our drug candidates are time consuming and expensive and together take several years or more to complete. Delays in regulatory approvals or rejections of applications for regulatory approval in the United States, the PRC or other markets may result from many factors, including:

- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials;

- regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- clinical holds, or partial clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- failure to reach agreement with the FDA, NMPA or other regulators regarding the scope or design of our clinical trials;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- our inability to enroll a sufficient number of patients who meet the inclusion and exclusion criteria in a clinical trial;
- our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- clinical sites and investigators deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- failure of our third-party CROs to satisfy their contractual duties or regulatory requirements or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- unfavorable or inconclusive results of clinical trials and supportive nonclinical studies, including unfavorable results regarding effectiveness of drug candidates during clinical trials;
- feedback from the FDA, NMPA, an IRB, DSMB, EC or comparable entities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- decision by the FDA, NMPA, an IRB, DSMB, EC or comparable entities, or us to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to demonstrate a benefit from using a drug candidate;
- our inability to obtain approval from IRBs, DSMBs, or ECs to conduct clinical trials at their respective sites;
- manufacturing issues, including problems with manufacturing or timely obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; and
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs, DSMBs, or ECs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we are required to conduct additional clinical trials or other studies with respect to any of our drug candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these studies are not positive or are only modestly positive, we may be delayed in obtaining regulatory approval for that drug candidate, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. Our drug development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process. Significant clinical trial delays could allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates, if and when approved. If any of this occurs, our business will be materially harmed.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the drug candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our drug products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of drug candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our drug products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential drug candidates will be harmed.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, layoffs, changes in regulations or policies or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products or other regulatory filings can be affected by a variety of factors, including government budget and funding levels, government shutdowns, significant layoffs or turnovers, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. Layoffs in 2025 at several U.S. health agencies, including the FDA, the Department of Health and Human Services, the Centers for Disease Control and Prevention and the National Institutes of Health, have impacted the FDA's ability to review and approve new medicines and conduct necessary inspections. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to furlough employees and experience substantial funding cuts and pause or delay critical activities. In addition, government funding of the FDA, SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable, and spending allocation priorities may undergo significant changes through congressional budgeting and appropriations processes.

To the extent the FDA's normal operations are disrupted or delayed, for example due to travel restrictions, public health or geopolitical issues, staffing shortages, layoffs or lack of funding, the FDA may not be able to complete the necessary inspections or provide feedback in a timely manner during our clinical development or review period. If any such delays or disruptions were to occur, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable regulatory authorities in China and other jurisdictions. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the drug. The FDA may also require a REMS program as a condition of approval of our drug candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, NMPA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

The FDA may seek to impose a consent decree or withdraw marketing approval if compliance with regulatory requirements is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drug candidates, including adverse events, or AEs, of unanticipated severity or frequency, or with our third-party manufacturers or 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 our drug candidates, withdrawal of the product from the market or voluntary product recalls;
- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, NMPA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA, NMPA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of any of our drug candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. Other comparable regulatory authorities outside the United States, such as the NMPA, may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

Furthermore, our research operations and manufacturing facilities are in the PRC. The pharmaceutical industry in the PRC is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See “*Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation*” for a discussion of regulatory requirements that are applicable to our current and planned business activities in the PRC. In recent years, the regulatory framework in the PRC regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in the PRC and reduce the current benefits we believe are available to us from developing and manufacturing drugs in the PRC. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in the PRC. We believe our strategy and approach is aligned with the Chinese government’s policies, but we cannot ensure that our strategy and approach will continue to be aligned.

Risks related to commercialization

We are substantially dependent on the commercial success of Olverembatinib and Lisoftoclax. If we are unable to maintain or increase sales of Olverembatinib and Lisoftoclax, our ability to generate revenue and our financial condition will be adversely affected.

We are substantially dependent on the commercial success of Olverembatinib and Lisoftoclax, our only products approved for sale in China. Sales of Olverembatinib and Lisoftoclax in China accounted for substantially all of our revenues for the years ended December 31, 2024 and 2023, and although a substantial portion of our revenue for the year ended December 31, 2024 was related to intellectual property income and option payment received from Takeda under the Takeda Exclusive Option Agreement (as defined below), we expect our revenues to continue to be driven primarily by sales of Olverembatinib and Lisoftoclax in the near term. Our ability to successfully market Olverembatinib and Lisoftoclax and our other current and future drug candidates depends on numerous factors, including but not limited to those described elsewhere in this section, some of which are beyond our control. If we are unable to obtain regulatory approval for Olverembatinib and Lisoftoclax in the United States, or if we are unable to continue to commercialize Olverembatinib and Lisoftoclax successfully in China or commercialize our other current and future drug candidates or are unable to obtain a distributor or partner to commercialize them, we may generate substantially less revenue or may not be able to generate any revenue. This would result in an adverse effect on our business, financial condition, results of operations and growth prospects.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals for our drug candidates (including Olverembatinib and Lisoftoclax outside of China), we will not be able to commercialize our drug candidates in the markets that we desire, and our ability to generate revenue will be materially impaired.

We became a commercial-stage company in 2021 upon commercialization of Olverembatinib and Lisoftoclax in China. We have not received regulatory approval to market Olverembatinib and Lisoftoclax in the United States or any market outside of China and, other than Olverembatinib and Lisoftoclax, do not have any drug candidates that have gained regulatory approval for sale in the United States, the PRC or any other country, and we cannot guarantee that we will ever have internally developed drugs approved for commercialization outside of China. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize our drug candidates in a timely manner. We cannot commercialize any products or drug candidates without first obtaining regulatory approval to market each drug from the FDA, NMPA and/or comparable regulatory authorities. We are currently conducting Phase 3 registrational trials for Olverembatinib and Lisoftoclax in the United States and in other countries outside of China, and certain of our other drug candidates are also currently undergoing clinical trials. We cannot predict whether these trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Regulatory authorities outside of the United States, such as the NMPA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time consuming. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all. For details of requirements to obtain regulatory approvals in the PRC or the United States, please see the section titled “*Item 4. Information on the Company—B. Business Overview—Government regulation.*”

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the United States and the PRC, and approval is never guaranteed. Even if Olverembatinib and Lisoftoclax and our other drug candidates were to successfully obtain approval from the relevant regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the FDA, NMPA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

We have and may continue to license commercialization or other rights and pursue other forms of collaboration worldwide, which can expose us to additional risks of conducting business in additional international markets.

Non-U.S. markets are an important component of our growth strategy. We intend to focus on additional opportunities in the PRC, in particular, but may also pursue partnerships in other geographies. Our ability to enter into partnerships will depend in large part on whether we are able to successfully demonstrate that our small-molecule drug candidates are attractive novel therapies for cancer. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- changes in a specific country's 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;
- economic weakness, including inflation or political instability, particularly in non-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- 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, particularly in non-U.S. countries where labor unrest is more common than in the United States;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a non-U.S. market with low or lower prices rather than buying them locally;
- failure of our employees, agents, representatives, business partners and third-party intermediaries to comply with the rules and regulations of the U.S. Treasury Department's Office of Foreign Assets Control, or OFAC, and the Foreign Corrupt Practices Act of 1977, or the FCPA;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions such as physical damage to our facilities and those of our third-party service providers, loss or spoilage of inventory, power outages, telecommunications, transportation or other infrastructure failure, cybersecurity incidents and other business interruptions resulting from geopolitical events, including war and terrorism, or natural and man-made disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes, fires, drought, extreme heat, blizzards and other extreme weather conditions.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

We have limited commercialization experience, and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our other products that receive regulatory approval on our own or together with collaborators.

We have limited experience as a commercial organization, and we have no commercialization experience in the United States. Although we have commercialized Olverembatinib and Lisoftoclax in China, we may lack the necessary expertise, personnel and resources to successfully commercialize Olverembatinib and Lisoftoclax in the United States or any other key global markets, and we may not be successful in commercializing any of our other products that receive regulatory approval on our own or together with collaborators, if at all.

Factors that may affect our ability to commercialize any of our drug candidates on our own include, but are not limited to, recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our drug candidates and other unforeseen costs associated with expanding our sales and marketing organization outside of China. Developing a sales and marketing organization in a new market requires significant investment, is time-consuming and could delay the launch of our drug candidates. We may not be able to build an effective sales and marketing organization in the United States or other key global markets. If we are unable to build our own sales and marketing capabilities or to find suitable partners for the commercialization of our drug candidates, we may have difficulties generating revenue from them.

If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or whether they will have effective sales forces. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates.

There can be no assurance that we will be able to further develop and successfully maintain internal sales and commercial distribution capabilities outside of China 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 substantial product sales revenue.

We face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive and characterized by rapidly advancing technologies, with a strong emphasis on proprietary products. We face competition with respect to Olverembatinib and Lisoftoclax, our current drug candidates and any future drugs that we may develop or in-license from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies, including AbbVie, Enliven, Roche, BeOne, Terns, Novartis, Innocare, Oric, Agios, and Takeda that currently market and sell drugs or are pursuing the development of drugs that are addressing similar pathways and mechanisms of actions as our drug candidates. See “*Item 4. Information on the Company—B. Business Overview—Competition.*” 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.

Additionally, beyond companies targeting the same pathways, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. These new treatments can change the standard of care, and tolerance for safety and expectations for efficacy and can also impact the addressable patient population, the adoption of our drug candidates, if approved, by patients and healthcare providers and payors as well as pricing and reimbursement.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain approval from the FDA, NMPA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and or slow our regulatory approval.

Our drug candidates, if approved under an NDA, could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012 established a user fee program to generate hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, could significantly decrease the timeframe for FDA review and approval of generic drug applications. In addition, the pricing of our drug candidates depends, and if and when approved for marketing, will depend, in part, on the pricing strategies adopted by our competitors. If we or our partners are forced to reduce the prices of our drug candidates, or if sales of our drug candidates fall, due to competitive pricing, our revenue will be negatively affected.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful; second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, mAb drugs, tumor targeted small molecules or a combination of these. Third line therapies can include bone marrow transplantation, mAb and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, we expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our drug candidates may be limited or may not be amenable to treatment with our drug candidates. Even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first-or second-line therapy.

Our market opportunities may also be limited by competitor treatments that may enter the market. See “*—We face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do.*”

Any of our drug candidates that receive regulatory approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Any of our drug candidates that receive regulatory approval may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drug candidates, if approved, as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, NMPA or other comparable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;

- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

Certain of our drug candidates represent a departure from more commonly used methods for cancer treatment, and potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than any of our drug candidates, if approved. This may have a material impact on our ability to generate revenues from our drug candidates. Further, given the novelty of our drug candidates, the end users and medical personnel may require a substantial amount of education and training.

If our drug candidates fail to achieve or maintain market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost effective or render our drug candidates obsolete.

We currently manufacture, and intend to continue to manufacture, at least a portion of our drug candidates ourselves. Delays in completing and receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our revenues and growth.

Our Suzhou facility, our global research and development center and manufacturing facility, has more than 200,000 square feet of space, and the manufacturing capacity for both oral solid tablets and capsules is up to 250 million dosage units per year. We also maintain manufacturing capability for lyophilized formulations at the Suzhou center, and we lease a facility in China Medical City, Taizhou, Jiangsu Province, China, where we produce and supply preclinical test articles and clinical trial materials for some of our drug candidates.

In addition to the risks described in “—*Risks related to our reliance on third parties*,” our manufacturing facilities will be subject to ongoing, periodic inspection by the FDA, NMPA or other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates. We also may encounter problems with the following:

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

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business. Developing advanced manufacturing techniques and process controls is required to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand for any of our drug candidates, if approved, we will need to increase, or “scale up,” the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our drug candidates in a sufficient quantity to meet future demand.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our drug candidates or any future drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a drug product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example:

- changes to our manufacturing arrangements;
- additions or modifications to drug product labeling;
- changes to reimbursement in government-funded healthcare programs;
- the recall or discontinuation of our drug products; or
- additional record-keeping requirements.

If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. In December 2020, the U.S. Centers for Medicare & Medicaid Services, or CMS, issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. The American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business.

In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Further, the Inflation Reduction Act of 2022, or the IRA, among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

The Bipartisan Budget Act of 2018 also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has published a final rule to give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other legislative changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2032, unless Congress takes further action.

Further, the OBBA has enacted, among others, changes to eligibility requirements for premium tax credits, which has resulted, and is expected to result, in less coverage in the ACA's health insurance marketplace ("Marketplace") over the next few years and has made other changes to the enrollment and eligibility requirements for Medicaid. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional challenges and healthcare reform measures under the current U.S. administration will impact the ACA. For example, the CMS recently proposed two mandatory payment model pilots, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Model, focused on Part D drugs, and Global Benchmark for Efficient Drug Pricing ("GLOBE"), focused on Part B drugs, which will require pharmaceutical companies to pay additional rebates on certain medicine whose U.S. net-of-discount prices exceed those in certain other countries. Complying with any new legislation and regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the IRA includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, such as directing the federal government to negotiate a maximum fair price for certain higher-cost single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries and impose new required discounts on manufacturers, among other changes. Various industry stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of IRA are unconstitutional. The impact of these judicial challenges as well as other legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current U.S. administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms, including any potential expansion of government price controls, may prevent us from being able to generate revenue, attain profitability, or commercialize our drug candidates, if approved.

If our drug candidates obtain marketing approval in the United States, the 340B Drug Pricing Program may require us to provide significant discounts on outpatient drugs to eligible healthcare organizations. The program has expanded substantially in recent years, and further expansion of the 340B program, the number of covered entities, or contract pharmacy arrangements could negatively impact our revenues and results of operations. Sales under the 340B program are made at a significant discount to our wholesale acquisition cost. Growth in 340B-eligible purchases as a percentage of our total U.S. sales could negatively impact our net revenues and gross margins.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our drug products, once approved, or put pressure on our drug product pricing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our drug products. Further, FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited period of time to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida, while other states await FDA approval. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

In addition, recent legislative and regulatory proposals in the United States have included "most favored nation", or MFN, drug pricing policies designed to align the prices in the U.S. with the lower prices in other countries. If enacted, this could affect profitability for any of our drug candidates that obtain marketing approval in the U.S., if any, as well as in other countries, as a price referencing policy to the U.S. market could make it commercially unviable to launch in a price constrained market. There are investigations underway to examine price differentials and consider policy approaches for implementation, including through administrative action. To the extent that such regulatory and policy changes have a negative impact on us, including through adverse implications in drug pricing and local market access, such changes could adversely impact our business, results of operations and financial position.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA, the IRA or new legislation. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare or impose price controls may adversely affect:

- the demand for our drug candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our drug products;
- our ability to obtain coverage and reimbursement approval for a drug product;

- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved drug 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent the trajectory of these legislative and regulatory proposals will be implemented by the federal and state governments, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. Further, recent policy changes affecting the FDA have resulted in significant changes to research, testing, regulatory approval or clearance, manufacturing and marketing of FDA-regulated products. The FDA has also adopted certain programs, including the PreCheck Program and Commissioner's National Priority Review Voucher Program, designed to increase domestic production of FDA-regulated products and increased enforcement activities by issuing larger numbers of warning letters to pharmaceutical companies related to violation of regulatory standards governing direct-to-consumer advertising. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Changes to healthcare regulation and policies, agency priorities, enforcement initiatives and focus, and coverage and reimbursement for healthcare products and services may be sudden and unexpected, and we may experience increased costs to monitor for such changes and respond to any new requirements affecting our business and operations.

There is also a great degree of uncertainty regarding how the U.S. Supreme Court decisions, including *Loper Bright Enterprises v. Raimondo* and *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, will impact enforcement and decision-making authority of regulatory agencies, including those of the FDA. *Loper Bright* explicitly overturned Chevron deference, which previously gave judicial deference to administrative action by agencies in the executive branch. Further, the Supreme Court's decision in *Corner Post* may result in challenges to FDA decisions by new litigants long into the future, resulting in greater uncertainty about our continued operations. In February 2025, an executive order was signed asserting greater authority over all federal agencies, including those established by Congress as independent from direct presidential control. The executive order may lead to delays, if not cancellations, of pending and proposed regulations at federal agencies and introduces uncertainty as it subjects all significant regulatory actions by the agencies to the President's supervision and control. We cannot predict the impact that such executive order, any future executive orders or legislation implementing executive orders may have on our business or our results of operations.

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

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our drug products for which we obtain marketing approval. Similarly, our participation in the federal health care programs and acceptance of federal grant funding may subject us to federal false claims laws, civil penalties and assessments, criminal prosecution, and other administrative, civil, and criminal remedies.

In addition, once our product is approved in the U.S. we may be subject to transparency laws and patient privacy and security regulation by both the U.S. federal government and the states in which we conduct our business.

Once we have an approved product in the U.S., the laws in the U.S. that may affect our ability to operate include, but are not limited to, the following examples:

- The federal Anti-Kickback Statute, or AKS, prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying 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, lease, or order of, or the arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. 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. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending or arranging for the prescription or purchase of any drug product may be subject to scrutiny if they do not qualify for an exception or safe harbor. This law would apply to our marketing practices, educational programs, pricing policies, and relationships with healthcare providers. We continue to evaluate what effect, if any, these rules will have on our business.
- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act, or FCA, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS or the FDCA constitute a false or fraudulent claim for purposes of the FCA. Promotion that is deemed to be “off label” can also be the basis of FCA exposure.
- The federal Civil Monetary Penalties law prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations imposes criminal and civil liability for fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs. Similar to the federal AKS, 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. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs, or integrity oversight and reporting obligations to resolve allegations of non-compliance.
- Privacy and data security laws may apply to our business. Under Section 5(a) of the Federal Trade Commission Act, the Federal Trade Commission, or the FTC, expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule. States may also impose requirements, for example the California Consumer Privacy Act created data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information and other states have adopted consumer privacy laws and regulations, including those specific to health information. HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys’ fees and costs. While we are not currently a covered entity or a business associate under HIPAA, our future operations could subject us to HIPAA as a business associate or covered entity, depending on the scope of such operations.

- The federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments or other transfers of value made or distributed to physicians, certain non-physician practitioners and teaching hospitals, as well as ownership and investment interests held by such healthcare provider and their immediate family members. While we are currently not subject to the Physician Payments Sunshine Act, if our products are approved in the U.S., this may become applicable to us.
- For both investigational and commercialized products, interactions with or communications directed to healthcare providers, patients or patient- or disease-advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non-misleading sharing of information regarding products in development and off-label uses including dissemination of peer-reviewed reprints, support of independent continuing medical education, and healthcare economic discussions with payors. In a competitive environment, a company’s communications about products in development may also be subject to heightened scrutiny.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor (i.e., even for self-pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and
- Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products.

In addition to FDA restrictions on the marketing of pharmaceutical products, pharmaceutical manufacturers who obtain FDA approval for any drug candidates and who begin commercializing those drugs in the United States may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. The activities of pharmaceutical manufacturers are also subject to regulation by numerous regulatory authorities including CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, or the FTC, the Occupational Safety & Health Administration, the Department of Commerce, the Environmental Protection Agency, and state and local governments. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, pharmaceutical manufacturers who have approved drug products on the market may be subject to patient privacy regulation by both the federal government and the states in which they conduct business. If any of our drug candidates, including Olverembatinib and Lisoftoclax in the United States, are approved, our operations may be subject to such patient privacy regulations.

Additionally, we may be subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Because of the breadth of these laws and regulations, and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws or regulations.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, disgorgement, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing these laws and regulations, and it is possible that some of our practices may be challenged under these laws or regulations. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare and other laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude or perceive that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse, healthcare, or other laws and regulations. If we fail or are perceived to fail to comply with any such laws or regulations, or any litigation, investigation, proceeding, or other action is initiated against us, including if we are not successful in defending ourselves or asserting our rights, it could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, remedial measures, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational and financial harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities.

If and when we are subject to these U.S. laws, ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Office of Inspector General advisory opinions, and special fraud alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the federal AKS are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including activities to be conducted by our sales team, were to be 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 civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations.

Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these 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 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.

We are subject to stringent and often unsettled laws, regulations, policies and contractual obligations related to privacy, data protection and information security, and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.

We are subject to privacy, data protection and information security laws and regulations that apply to the collection, transmission, storage and use of personal information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy, data protection and information security continues to evolve in jurisdictions worldwide, and there has been an increasing focus on these issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to properly protect the privacy and security of personal information, we could be found to have breached our policies or contracts. Further, if we fail to comply with applicable privacy and data protection laws and regulations, including in connection with our clinical trials, we could face significant administrative, civil and criminal penalties. In addition to federal regulators, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy or security of the personal information of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Privacy, data protection and information security regulation is evolving at both the domestic and international level. Laws in all 50 U.S. states require businesses to provide notice under certain circumstances to governmental authorities and affected individuals in connection with certain breaches of personal information, and, in the future, we may be required to notify applicable governmental authorities and affected individuals in the event of a data breach or other data security incident. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or CPRA and collectively, CCPA, and approximately one-third of U.S. states have enacted new data protection and privacy rights, requiring covered companies to grant rights to consumers regarding their personal information and implement processes to enable consumers to exercise their rights. Certain of these laws provide a private right of action for certain data breaches or provide for administrative fines, including the CCPA, among others, which provides for administrative fines of up to US\$7,500 per violation and allows private litigants affected by certain data breaches to recover potentially significant statutory damages. In addition to these omnibus state laws, states have enacted laws and regulations relating to other aspects of privacy and information security, including certain sector-specific laws, such as Washington's My Health, My Data Act. Similar laws are being considered in several other states, as well as the federal and local levels, reflecting a global trend toward more stringent privacy and information security legislation. The laws are not consistent, as certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international, or other state laws, and such laws may differ from each other, which may complicate compliance efforts. State laws are changing rapidly and there is discussion in Congress of a new comprehensive federal data protection law to which we may become subject if it is enacted, which may add additional complexity, variation in requirements, restrictions and potential legal risks, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data, and could result in increased compliance costs or changes in business practices and policies. These laws may apply directly to our business or indirectly by contract when we provide services to other companies. If we become subject to these new or additional privacy laws, the risk of enforcement actions against us could increase.

In addition, the European Union's General Data Protection Regulation (EU) 2016/679, or GDPR, went into effect on May 25, 2018 in respect of processing operations carried out in the context of the activities of an establishment in the European Union and any processing relating to the offering of goods or services to individuals in the European Union and/or the monitoring of their behavior in the European Union. Also, notwithstanding the United Kingdom's withdrawal from the European Union, by operation of the so-called UK GDPR, the GDPR continues to apply in substantially equivalent form to processing operations carried out in the context of the activities of an establishment in the United Kingdom, and any processing relating to the offering of goods or services to individuals in the United Kingdom and/or monitoring of their behavior in the United Kingdom. Accordingly, where we refer to the GDPR, we are referring to the UK GDPR in the context of processing operations in the United Kingdom, unless the context requires otherwise.

The GDPR provides that European Union member states and the United Kingdom may make their own further laws and regulations to introduce specific requirements in certain areas, including related to the processing of special categories of personal data,⁷ including personal data related to health and genetic data. This may lead to greater divergence among the laws and regulations that apply to the processing of personal data across the European Union and United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such laws and regulations could also limit our ability to collect, use, share and otherwise process personal data in the context of our European Union and/or United Kingdom establishments (regardless of where any such processing occurs), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

The GDPR imposes accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. The GDPR imposes certain other onerous obligations, including: obligations for controllers and processors to appoint data protection officers in certain circumstances; increased transparency obligations to data subjects for controllers; obligations to honor increased rights for data subjects; obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; and the obligation to provide notice of certain significant personal data breaches to the relevant supervisory authorities and affected individuals. In addition, the GDPR provides an expansive definition of personal data (including, for example, 'pseudonymized' and key-coded data).

The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union and United Kingdom, including the United States, known as 'third countries,' in respect of which the European Commission or other relevant regulatory body has not issued a so-called 'adequacy decision', unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This is an area of evolving complexity and achieving effective compliance with changing requirements and guidance in relation to data transfers from the European Union and United Kingdom is challenging. Standard contractual clauses approved by the European Commission and/or United Kingdom's Information Commissioner's Office (as applicable) remain, in principle, a basis on which to effect such transfers, but the standard contractual clauses alone may not suffice in all circumstances. Use of the standard contractual clauses must be assessed on a case-by-case basis, taking into account the legal regime applicable in the destination country. If we are unable to implement sufficient safeguards to ensure that any transfers of personal data from the European Union and United Kingdom are lawful, we may face increased exposure to regulatory action(s), substantial fines and injunctions against processing personal data from the European Union and United Kingdom. An inability to lawfully transfer personal data out of the European Union and United Kingdom to the United States or any other jurisdictions may (1) restrict our activities in the European Union and United Kingdom, (2) limit our ability to conduct clinical trials in the European Union and United Kingdom and/or to work with partners, service providers, contractors and other companies subject to European data protection laws and regulations and/or (3) require us to increase our data processing capabilities in the European Union and United Kingdom at significant expense or otherwise cause us to change the geographical location or segregation of our relevant systems and operations, any or all of which could adversely affect our financial results. Additionally, other countries outside of the European Union and United Kingdom and Switzerland have passed or are considering passing similar cross-border data transfer restrictions and laws and regulations requiring local data residency, which could increase the cost and complexity of operating our business.

Fines for non-compliance with the GDPR are significant—the greater of €20 million or 4% of global turnover (and the higher of £17.5 million or 4% of global turnover in the case of the UK GDPR). A wide variety of other potential enforcement powers are available to competent supervisory authorities in respect of potential and suspected violations of the GDPR, including extensive audit and inspection rights and powers to order bans on all or some personal data processing. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

In addition, any actual or alleged breach or violation of privacy, data protection or information security laws or regulations, particularly those resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized access to, or use or disclosure of, sensitive or confidential patient information, could have a material adverse effect on our business, reputation and financial condition. While we attempt to mitigate these associated risks, there is no assurance that our own privacy, data protection and information security-related safeguards will protect us from all risks associated with the processing, storage and transmission of such information.

Working to comply with the GDPR has required substantial efforts, and we expect that it will continue to be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices. Despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our activities carried out in the context of our operations in the European Union and the United Kingdom.

It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our practices and our compliance efforts may be, or may be alleged to be, unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape. Any actual or perceived failure to comply with federal, state or international laws or regulations, policies or contractual obligations regarding privacy, data protection, or information security could expose us to penalties, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also harm our business, financial condition, results of operations or prospects.

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

The FDA 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, or our employees or contractors, 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 our drug candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our drug candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current drug products could limit our ability to market those drug products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 product licensing approval is granted. For example, Olverembatinib was included in the 2022 National Reimbursement Drug List in China, which became effective March 2023. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. We might obtain marketing approval for a drug product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if any drug candidates we may develop obtain marketing approval.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our drug candidates will depend in part on the extent to which coverage and adequate reimbursement for these drug products 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 which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other future drug candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our drug candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement are not available, or is available only to limited levels, we may not be able to successfully commercialize our drug candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement levels for products can differ significantly from payor to payor. A decision by CMS or a third-party payor not to cover any product candidates we may develop could reduce utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our drug products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in the European Union may be more conservative than CMS. 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 reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drug products we may develop could have a material adverse effect on our financial position, results of operations and our ability to raise capital needed to commercialize drug candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved drug products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our drug products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our drug candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

A variety of risks associated with testing, manufacturing, marketing and other activities in connection with our drug candidates internationally may materially adversely affect our business.

We plan to eventually seek regulatory approval of our drug candidates (including Olverembatinib and Lisoftoclax) in many jurisdictions in addition to the PRC, including in the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- impact of global health emergencies, including pandemics and epidemics, on our ability to produce our drug candidates and conduct clinical trials in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;

- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common;
- delays or restrictions related to differing foreign investment laws and regulations;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent;
- 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.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations. In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, the U.S. government has issued a Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients with comments due within twenty-one days from the date of publication in the Federal Register, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We contract with WuXi STA, a subsidiary of WuXi AppTec, that manufactures certain of our active pharmaceutical ingredients. WuXi had been initially identified as a 'company of concern' in the proposed BIOSECURE Act, which may have restricted WuXi's business in the U.S. or the ability of businesses in the U.S. to conduct business with WuXi. The BIOSECURE Act was signed into law on December 18, 2025, and while WuXi is not currently listed as a 'company of concern', such a designation is still under consideration by other governmental departments.

We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our drug candidates to any of our customers or service providers, we could experience significant delays in the development or commercialization of our product candidates, and our business, liquidity, financial condition and/or results of operations could be materially and adversely affected. For additional detail, see *"Risks related to doing business in the PRC—The tension in international trade, rising political tension and increasing geopolitical risks, particularly between the United States and China, pose significant challenges that may adversely impact our business, results of operations and financial condition."*

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 drug products for which we have or will obtain regulatory approval (including Olverembatinib and Lisoftoclax) and may adversely affect our sales and profitability. Unapproved foreign imports of prescription drugs are illegal under the current laws of the United States, 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 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 brand names. In addition, theft 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, business, financial condition and results of operations.

Risks related to our intellectual property

If we are unable to protect and defend our proprietary technology or obtain and maintain patent protection for our drug candidates, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States, the PRC and other countries with respect to our proprietary technology and drug candidates.

We have sought to protect our proprietary position by filing patent applications in the United States, the PRC and other countries related to novel technologies and drug candidates that we consider important to our business. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future. This process is expensive and time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with our proprietary technology and drug candidates.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. In fact, patent applications may not issue as patents at all. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Furthermore, changes in either the patent laws or interpretation of the patent laws in the United States, the PRC and other countries may diminish the value of our patents or narrow the scope of our patent protection. We may not be aware of all third-party intellectual property rights potentially relating to our proprietary technologies and drug candidates. Other parties have developed technologies that may be related to or competitive with our own technologies and such parties may have filed or may file patent applications or may have obtained or may obtain patents claiming inventions that may overlap or conflict with those claimed in our own or licensed patent applications or issued patents. Additionally, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. There is also no assurance that all of the potentially relevant prior art relating to our owned and licensed patents and patent applications has been found, which could be used by a third party to challenge the validity or enforceability of our owned and licensed patents and patent applications, should they issue, or prevent a patent application from issuing. Any of the foregoing could harm our competitive position, business, financial condition, results of operations or prospects.

There can be no assurance that our or our licensors' pending patent applications will result in issued patents in jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patent rights by developing similar or alternative technologies or drug candidates in a non-infringing manner. If the patent protection provided by the patents and patent applications we own or license is not sufficiently broad to impede such competition, our ability to successfully commercialize our proprietary technologies and drug candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and prospects. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged, deemed unenforceable or invalidated in the courts or patent offices. We or our licensors may become involved in interference, inter partes review, post grant review, ex parte reexamination, derivation, opposition, challenges in judicial court, or other similar proceedings challenging our patent rights or the patent rights of others. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Some of our owned and licensed patents and patent applications may be co-owned with third parties. For example, one of our licensed patent families is co-owned with a third party. If we are unable to obtain an exclusive license to any such third party co-owner's interest in such patents and patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our owned and licensed patents to enforce such patents against third parties, and such cooperation may not be provided to us.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in other jurisdictions. In some cases, we or our licensors may not be able to obtain patent protection for certain proprietary technologies and drug candidates outside the United States. In addition, the laws of different jurisdictions provide different degrees of protection of intellectual property rights.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into all countries. We may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into all countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in other jurisdictions. These drugs may compete with our drug candidates, and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including the PRC. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights.

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

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Such proceedings could put our owned or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims of infringement, misappropriation or other intellectual property violation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical drug candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our drug candidates or which effectively prevent others from commercializing competitive drug candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review and inter partes review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our drug candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our drug candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our drug candidates but that are not covered by the claims of the patents that we own or license, or may own or license in the future;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license, or may own or license in the future;

- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license, or may own or license in the future, will not lead to issued patents;
- issued patents that we own or license, or may own or license in the future, may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a nonexclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain 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, it could significantly harm our business, results of operations and prospects.

We may become involved in lawsuits to protect, enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or in patent offices.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to protect, enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to protect, enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our owned or licensed intellectual property. Proceedings to enforce our patent and other intellectual property rights could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent rights or other intellectual property rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent rights or other intellectual property rights do not cover the technology in question. An adverse result in any litigation proceeding could put our owned or licensed patents, as well as any patents that may be issued in the future from our owned or licensed pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce our owned or licensed patents, or any patents that may be issued in the future from our owned or licensed patent applications that relate to one of our drug candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. In patent litigation in the United States and the PRC, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies, even outside the context of litigation, through mechanisms such as ex parte re-examination, inter partes review, post-grant review, derivation, opposition proceedings and equivalent proceedings. Such proceedings could result in revocation or amendment to our owned or licensed patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not provide extensive protection for those rights. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims challenging the inventorship or ownership of our owned and licensed patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we or our licensors may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our owned or licensed patents or other intellectual property as inventors or co-inventors. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose rights such as exclusive ownership of, or right to use, our patent rights or other owned or licensed intellectual property. Such an adverse determination may also result in a loss of freedom to operate, or in patent claims or exclusivity rights drugs being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and drug candidates, without payment to us, or could limit the duration of the patent protection covering our proprietary technology and drug candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our proprietary technology and drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies or drug candidates. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our avoiding infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including inter partes review, post grant review, interference and ex parte reexamination proceedings and oppositions or other comparable proceedings. Given the vast number of patents in our field of technology, we cannot be certain or guarantee that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others. For example, we are aware of patents owned by third parties that have generic composition of matter or method of use claims that may relate to certain of our product candidates. Any challenge to the validity of these patents may be unsuccessful, and courts or patent offices in the United States, the PRC and elsewhere could uphold the validity of any such patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent claims.

Third parties may assert that we are employing their proprietary technology, including patents and other intellectual property, without authorization. There may be additional third-party patents and patent applications of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the current or future use or manufacture of our drug candidates. Given that patent applications can take around 18 months or longer to be published, there may be currently unpublished patent applications that could be relevant to the use or manufacture of our drug candidates and give rise to infringement risks if such patent applications become issued patents. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to prevent us from commercializing such drug candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any such third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtain a license, limit our uses or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Third parties who bring successful claims against us for infringement, misappropriation or other violation of their intellectual property rights may obtain injunctive or other equitable relief, which could prevent us from developing, manufacturing and commercializing one or more of our drug candidates or other proprietary technology. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation of intellectual property against us, we may have to pay substantial damages, including treble 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. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. We cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms, and we may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Also, in the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical personnel, management personnel, or both from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of the ADSs and our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources.

Overall, 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.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our ordinary shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of the ADSs and ordinary shares may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our drug candidates to market.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and drug candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and drug candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our drug candidates could have been filed by others without our knowledge. It is also difficult for industry participants, including us, to identify these third-party patents and patent applications because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Further, the scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or drug candidates are not covered by a third party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and drug candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe.

As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our drug candidates that are held to be infringing. We might, if possible, also be forced to redesign drug candidates or services so that we no longer infringe the third-party's intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

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

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application would be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (1) file any patent application related to our drug candidates and other proprietary technologies we may develop; or (2) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included several significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned and in-licensed patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

U.S. law relating to the patentability of certain inventions in the life sciences industry is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future. The U.S. Supreme Court and federal courts have ruled on several patent cases in recent years that impact the scope of patentability of certain inventions or discoveries related to the life sciences, including both narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products, and could jeopardize or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable our patent rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For example, the U.S. Supreme Court held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the U.S. Patent Act, 35 U.S.C. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Additionally, other decisions in prior years found that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a “sufficient” additional feature is uncertain. Depending on future actions and/or decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

In 2012, the European Union Patent Package, or the EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or the UPC, for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC’s existence, the UPC legislation allows a patent owner to opt for its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and drug candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

We cannot predict how decisions by courts or the applicable government entity may impact the value of our owned and licensed patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects. Depending on future actions by courts and applicable government entities, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our or licensed intellectual property in the future. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on our owned and licensed patents and patent applications are due to be paid to patent agencies in various jurisdictions in several stages over the lifetime of the patent. Various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We are in some cases dependent on our outside counsel or our licensing partners to take the necessary action to comply with these requirements with respect to our owned and licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The terms of our patents may not be sufficient to effectively protect our drug candidates and business, and we may need to obtain patent term extensions and equivalent extensions outside of the United States.

In most countries in which we file, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords is limited.

In particular, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product 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. In the European Union, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and can be extended for an additional six months if data from clinical trials is obtained in accordance with an agreed-upon pediatric investigation plan. Although all countries in the European Union must, in accordance with applicable EU legislation, provide supplementary protection certificates, there is no unified procedure among countries in the European Union and so supplementary protection certificates must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be provided at all.

We may not be granted any extensions for which we apply in the United States or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In 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 are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may be able to enter the market sooner, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if patents covering our drug candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our owned or licensed patents in court, and we or our licensors may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents, or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, and our business and results of operations may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets or confidential information, including alleged trade secrets, of their former employers.

We also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality agreements with our employees and consultants. However, 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 these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Further, 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. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. We may also lose personnel as a result of such claims, and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Competitors or third parties could purchase our proprietary technologies or drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside the scope of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Relatedly, 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, which may result in claims by or against us related to the ownership of such intellectual property. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting 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 against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

Because our programs may involve additional drug candidates that may require the use of additional intellectual property or proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use or other third-party intellectual property rights from third parties that we identify as necessary for our proprietary technology or drug candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may be required to expend significant time and resources to redesign our proprietary technology or drug candidates, or to develop or license replacement technology, and our business, financial condition and prospects for growth could suffer.

Our rights to develop and commercialize our technology and drug candidates may be subject, in part, to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into license agreements with third parties, including the University of Michigan, for rights related to certain of our drug candidates, and we may enter into additional license agreements in the future with others to advance our research or allow commercialization of drug candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. Additionally, our current license agreements impose, and future agreements may impose various development, diligence and other obligations on us.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the technology that we license from third parties. In such an event, 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 or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. 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 competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, drug candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, drug candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

For more information on the terms of our license agreements with the University of Michigan, see “Item 4. Information on the Company—B. Business Overview—Agreements with the University of Michigan.”

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

We are heavily reliant upon licenses from third parties to certain patent rights and proprietary technology that are important to or necessary to the development of our technology and drug candidates, including licenses we are granted through our agreements with the University of Michigan. Disputes may arise between us and our licensors or licensees regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor or licensee that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our proprietary technologies and drug candidates.

The agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

In spite of our best efforts, our counterparties might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements, including our agreements with the University of Michigan. If these licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

For more information on the terms of our license agreements with the University of Michigan, see “*Item 4. Information on the Company—B. Business Overview—Agreements with the University of Michigan.*”

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. The inquiry may progress to a claim that we or our employees inadvertently or otherwise breached the agreement and used trade secrets or other information proprietary to the third party. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our drug candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our drug candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Patent protection and patent prosecution for some of our drug candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our drug candidates, there may be times when the filing and prosecution activities for patents relating to our drug candidates are controlled by our licensors or collaboration partners. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our drug candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those drug candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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.

Our current and future trademark applications in the United States and in foreign jurisdictions may not be allowed or may subsequently be opposed. Once filed and registered, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our reliance on third parties

We rely on third parties to manufacture a portion of our drug candidate supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our drug candidates, including Olverembatinib and Lisoftoclax. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we currently have manufacturing facilities in the PRC that support our clinical and commercial production, we partially rely on outside vendors to manufacture supplies and process our drug candidates, including Olverembatinib and Lisoftoclax. We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, NMPA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;

- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our drug candidates, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drug candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- our third-party manufacturers could breach or terminate their agreement with us; and

Each of these and other risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the FDA, NMPA or other comparable regulatory authorities, result in higher costs or adversely impact commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA, NMPA or other comparable regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

The manufacture of drugs is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us.

Manufacturers of drug often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before a third party can begin commercial manufacture of our drug candidates, contract manufacturers are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture our drug candidates, any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a cost-effective manner in order for us to obtain regulatory approval of our drug candidates. If our contract manufacturers do not pass their inspections by the FDA, NMPA or other comparable regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates. In addition, drug manufacturing facilities are continuously subject to inspection by the FDA, NMPA and other comparable regulatory authorities, before and after drug approval, and must comply with cGMPs. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drug candidates, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial condition and results of operations.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, could require prior review by the FDA, NMPA or other comparable regulatory authorities and/or approval of the manufacturing process and procedures in accordance with the FDA or NMPA's regulations or comparable requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA, NMPA or other comparable regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

We are dependent on our suppliers, and the inability or other failure of suppliers to deliver necessary materials and components of our products at prices and volume and with specifications and performance characteristics acceptable to us, could materially harm our business.

Currently, our drug substance or API for our manufacturing activities are supplied by a single source supplier. We have agreements for the supply of drug substance with manufacturers that we currently believe have sufficient capacity to meet our demands. 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 or component defects. There is a risk that, if supplies are interrupted in any manner, including as a result of the BIOSECURE Act, it would materially harm our business. For additional detail, see *“Risks related to doing business in the PRC—The tension in international trade, rising political tension and increasing geopolitical risks, particularly between the United States and China, pose significant challenges that may adversely impact our business, results of operations and financial condition.”*

We have entered into collaborations and other relationships with leading biotechnology companies and research institutions and may form or seek other collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to Olverembatinib and Lisoftoclax, our other drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. We have also established collaborations and other relationships with leading biotechnology and pharmaceutical companies around the world, including a collaboration and license agreement with Innovent and clinical collaboration agreements with AstraZeneca, Merck and Pfizer, and research and development relationships with leading research institutions, such as Dana-Farber Cancer Institute, Mayo Clinic, MD Anderson Cancer Center, National Cancer Institute and the University of Michigan. See the section titled *“Item 4. Information on the Company—B. Business Overview—License, collaboration and agreements”* for more information. We cannot guarantee you that these third parties (which we refer to in this risk factor as collaborators) will not terminate their collaboration, or seek to change terms of the collaboration, with us. Additionally, in June 2024, we entered an exclusive option agreement where we granted Takeda an exclusive option to take an exclusive license (even as to us and our affiliates) to Olverembatinib in the Territory. We cannot guarantee that Takeda will not terminate the option agreement or seek to change the terms of the exclusive license prior to exercising the option, nor can we guarantee that Takeda will exercise the option at all.

We face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration, partnership, licenses or other arrangement will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, partnership, licenses or other arrangement and the proposed collaborator’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or applicable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to its ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Moreover, we may not be successful in our efforts to establishing or maintaining our collaborations, partnerships, licenses or other arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial potential. If and when we collaborate with a third party for the development and commercialization of a drug candidate, such as our strategic partnership with Innovent, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

Collaborations, partnerships, licenses and other similar arrangements are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

Further, collaborations, partnerships, licenses and other similar arrangements involving our drug candidates and are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding or other external factors that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain, enforce, protect or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations with entities or educational institutions in the United States may be suspended, terminated or otherwise adversely affected by escalating geopolitical tensions between the United States and China, which may be exacerbated by recent retaliatory tariff increases; and
- collaborators may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations, joint ventures, strategic partnerships or the license of any third-party drugs if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. If our existing collaborations are terminated or suspended, we may not be able to identify other suitable collaborators or reach agreement with other suitable collaborators on a timely basis, on acceptable terms or at all. If we are unable to continue our collaborations with our existing collaborators or are unable to identify or reach agreement with other suitable collaborators, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, increase our expenditures or needs for additional capital to pursue further development or commercialization of the applicable drug candidates or undertake development or commercialization activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We rely on our current and future partners' willingness and ability to devote resources to the development and commercialization of some of our products and product candidates and to otherwise support our business as contemplated in our partnership agreements, which may be terminated.

We rely on our current and future partners to support our business, including to assist with, or to conduct, clinical and regulatory development, manufacturing and/or commercialization of certain of our products and product candidates or to provide access to technologies, skills and information that we do not possess. For example, we have granted Innovent exclusive rights to develop with us our Olverembatinib in the PRC, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan and exclusive rights to commercialize Olverembatinib in certain cities within the PRC, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan. Additionally, in June 2024, we granted Takeda an exclusive option to take an exclusive license (even as to us and our affiliates) to Olverembatinib in the Territory, with potential additional payments and royalties, but we cannot guarantee you that Takeda will not terminate the option agreement or seek to change the terms of the exclusive license prior to exercising the option, nor can we guarantee that Takeda will exercise the option at all. If we do not realize the contemplated benefits from our current and expected partnerships, our business, financial condition and results of operations may be materially harmed.

In particular, the termination of our current and future partnerships could significantly impact the development and commercialization of our products and product candidates and impact our financial results and future prospects. For example, Innovent has the right to terminate the collaboration and license agreement concerning Olverembatinib at any time by providing 180 days' prior written notice to us; provided, that in the event we are not able to commercialize the licensed product in the cities which Innovent has exclusive rights to, we have certain rights and obligations.

Additionally, under our exclusive option agreement with Takeda, Takeda has the right to not elect to exercise the exclusive option and can terminate the agreement in its sole discretion upon written notice, among other options. Any disruption to our arrangement with Takeda or changes in Takeda's product development or business strategy for Olverembatinib could result in Takeda terminating the option agreement or seeking to amend the terms of such agreement or seek other changes that could ultimately cause a material decline in our expected revenue. Any failure by any current or future partner to perform its obligations under our agreements for any reason, including its obligations to make milestone payments or pay royalties, or modification or termination of such agreements, could have a material adverse effect on our financial performance.

We also expect we will continue to rely on certain of our current and future partners to periodically provide us with information about the status, progress and results of clinical trials and regulatory processes that they are conducting, sponsoring or pursuing with respect to our partnered products. With certain partners, we may not have direct access to the underlying data or direct communications with the relevant regulators.

In addition, our reliance on our current and future partners could subject us to a number of additional risks, including the following:

- our partners have significant discretion regarding whether and on what timeline to pursue planned activities;
- we cannot control the quantity and nature of the resources our partners may devote to the development, commercialization, marketing and distribution of products or product candidates;
- our partners may not develop products generated using our small-molecule technology as expected;
- disputes between us and our partners may delay or terminate the research, development or commercialization of the applicable products and product candidates or result in costly litigation or arbitration that diverts management's attention and resources;
- we may not receive milestone payments from our partners, at the expected time or at all, if our partners do not achieve future milestones or if we and our partners disagree about whether a milestone has been reached;
- with respect to collaborations, partnerships or other arrangements under which we have an active role, we and our partners may have differing opinions or priorities, or we may encounter challenges in joint decision making, which may delay or terminate the research, development or commercialization of the applicable products and product candidates;
- our partners may delay, terminate or repeat clinical trials or require a new formulation of a product candidate for clinical testing, or may abandon a product candidate;
- our relationships with our partners may divert significant time and effort of our scientific staff and management team;
- our partners may be subject to regulatory sanctions that could adversely affect the development, approval or commercialization of the applicable products or product candidates;
- our partners may not properly maintain or defend relevant intellectual property rights, or may infringe the intellectual property rights of third parties, or may use our or third parties' proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- our partners may develop competing products, therapeutic approaches or technologies;
- business combinations, financial difficulties or significant changes in a partner's business strategy may adversely affect that partner's willingness or ability to continue to pursue our products or product candidates; and
- our collaborations, partnerships, licenses or other arrangements that we rely or expect to rely on may be terminated, breached or allowed to expire, or our partners may reduce the scope of our agreements with them.

Any one or more of the foregoing risks, if realized, could have a material adverse effect on our business, financial condition and results of operations.

If we fail to maintain an effective distribution channel for our drug candidates, our business and sales could be adversely affected.

We have relied on, and plan to rely on, a number of third-party distributors to distribute Olverembatinib in China, including Innovent, and Lisaftoclax and we plan to rely on third-party distributors to distribute drug candidates in jurisdictions outside of China, if approved. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our drug candidates. However, we have relatively limited control over our distributors which may fail to distribute our drug candidates in the manner we contemplate. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our drug candidates to hospitals, medical institutions and sub-distributors, they may terminate their relationship with us. There is a risk that, if the distribution of our drug candidates is interrupted, our sales volumes and business prospects could be adversely affected.

We rely on third parties to conduct our preclinical studies and clinical trials, and we must work effectively with collaborators to develop our drug candidates. In many cases, our drug candidates, including Olverembatinib and Lisoftoclax, are studied in third-party studies, including investigator-initiated trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or fail to design, execute, and complete appropriate and timely studies of our drug candidates, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We do not currently have the ability to independently conduct clinical trials. We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, NMPA and other comparable regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or clinical investigators fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for certain restrictions imposed under our agreements with such CROs, we have limited ability to control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, we may need to enter into new arrangements with alternative third parties, our results of operations and the commercial prospects for our drug candidates may be harmed, our costs could increase and our ability to generate revenues could be delayed. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially influence our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval, and commercialize our drug candidates, including Olverembatinib and Lisoftoclax in the United States and other jurisdictions. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials for our licensed technology, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition and results of operations.

In many cases, our drug candidates, including Olverembatinib and Lisoftoclax, are included in preclinical studies and clinical trials, including investigator-initiated trials, over which we may have no or limited control. If they fail to design, execute, and complete appropriate and timely studies of our drug candidates or patients may experience AEs not related to our drug candidate that could still impact regulatory approval or market adoption by patients, healthcare providers and/or payors.

Risks related to our industry, business and operations

If our manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

In addition to the manufacturing risks described in “—Risks related to commercialization” and “—Risks related to our reliance on third parties,” if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA, NMPA or other comparable regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce sales of Olverembatinib and LISAFTOCLAX in China or our product sales if and when we are able to successfully commercialize one or more of our drug candidates, including Olverembatinib and LISAFTOCLAX in the United States and other jurisdictions.

Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including:

- equipment or technology malfunctions or failures;
- work stoppages;
- damage to or destruction of either facility due to natural disasters;
- regional power shortages;
- product tampering; or
- terrorist activities.

Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and results of operations.

Currently, we maintain insurance coverage against damage to our property and equipment. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. See “—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 may be unable to meet our requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

We have significantly increased our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.

Since our listing on the HKEx in 2019, we have significantly increased our research, development, manufacturing and commercial capabilities. As of December 31, 2025, we had approximately 767 full-time employees. As our development and commercialization plans and strategies develop, and as a result of becoming a Hong Kong and U.S.-listed public company, we must add a significant number of additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA or other comparable regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drug candidates (including Olverembatinib and LISAFTOCLAX) will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval of our drug candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates (including Olverembatinib and Lisoftoclax in the United States and other jurisdictions, if approved) and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain our key executives and scientists, and to attract, retain and motivate qualified personnel.

We are highly dependent on our executive officers, senior management, scientific teams, and scientific advisory board. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we may provide equity award grants from time to time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the price of our ordinary shares and ADSs that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Except with regard to Dr. Wang, we do not have formal employment or service agreements with our key management and scientific personnel, and our executives may terminate their employment with us at any time, with or without notice. We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, preclinical development and commercialization strategy. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

In addition, we have been, and from time to time may be, involved in labor disputes with our employees. Such disputes may divert our limited resources and management attention to defend the claims. The claims raised in such labor disputes may have an adverse impact on our reputation in the industry and/or as an employer. Furthermore, our insurance coverage may not be sufficient for such labor disputes. Therefore, any such labor disputes may have a material adverse impact on our reputation, business, financial condition, and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our officers, employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our drug candidates (including Olverembatinib and Lisoftoclax) and begin commercializing those drugs in the United States, our potential exposure under U.S. laws will increase significantly 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 education 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 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 commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by officers, 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 or our officers or employees 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 or our key employees, 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 significant fines or other sanctions.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. If we undertake acquisitions of businesses with access to promising markets or technologies, we may not be able to realize the benefits of such acquisitions, including if we are unable to successfully integrate them with our existing operations and company culture, or if we encounter difficulties in developing, manufacturing and marketing any new products resulting from such acquisitions.

We are subject to various governmental export control, trade sanctions, trade policies and tariffs and foreign investment laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate the relevant controls.

In some cases, our drug candidates may be subject to export control laws and regulations, including in some limited cases, the Export Administration Regulations administered by the U.S. Department of Commerce, and some of our activities may be subject to trade and economic sanctions, including those administered by OFAC, which we collectively refer to as trade controls. As such, in some cases, licenses may be required to export, import, re-export or transfer our drug candidates to certain countries and end users and for certain end uses. The process for obtaining necessary licenses and making required notices may be time-consuming or unsuccessful, potentially causing delays in sales or losses of sales opportunities. Trade controls are complex and dynamic regimes, and monitoring and ensuring compliance can be challenging.

In addition, following the geopolitical conflicts in Russia and Ukraine, several countries imposed certain economic sanctions and export control restrictions against Russia and Belarus and have continued to strengthen these controls. These controls include sanctions on certain Russian individuals and entities, including certain Russian banks, energy companies and defense companies as well as restrictions on the export of certain goods and the provision of certain services to and on new investment in Russia and Belarus. We currently are sponsoring some clinical trials in Russia through collaborations with CROs. Although we, and our CROs, have implemented measures designed to ensure our compliance with these controls, monitoring and ensuring compliance can be challenging. We believe that these clinical trials we are conducting in Russia do not give rise to sanctions or other regulatory encumbrances. Any or all of these factors could negatively affect our clinical development plans, financial condition and result of operations. For example, in response to additional restrictions, we could be required to close out clinical trials hosted in Russia. Any failure to comply with these regimes could subject us to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges and reputational harm. In addition, investigating or defending against any such allegations, actions or investigations could result in the diversion of management's attention and resources and significant defense costs and other professional fees.

In addition, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes and other limitations on cross-border operations. For example, the current U.S. administration has made and continues to make significant changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade, including imposing new tariffs on certain foreign goods or renegotiating, or potentially terminating, certain existing bilateral or multi-lateral trade agreements. Changes in U.S. trade policy have resulted in one or more trading partners adopting responsive or retaliatory trade policies, which may make it more difficult or costly for us to export our products to those countries. In addition, the U.S. Department of Commerce has initiated national security investigations into the importation of pharmaceuticals and pharmaceutical ingredients pursuant to Section 232 of the Trade Expansion Act of 1962, which could result in the imposition of new tariffs on imports within the pharmaceutical industry. Further, the U.S. announced a 100% tariff, on any branded or patented pharmaceuticals imported into the U.S. from drug manufacturers that do not have, or is not in the process of building, a manufacturing facility in the U.S., which has been delayed as negotiations with large drug manufacturers continue. The extent of the impact that such tariffs, trade policies, or new legislation or regulations will have on the company specifically, or on the U.S. market and global economy generally, are uncertain and in the long term, unpredictable, and could adversely affect our business, financial condition, and results of operations. In addition, the increased tariffs could impact our ability to commercialize Olverembatinib and Lisoftoclast in the U.S. or to develop and commercialize other drug candidates for the U.S. market, which is relevant to our ability to generate future revenues from these activities. Changes in trade policies and tariffs may have adverse implications on drug pricing, drug production levels and patient access, and may result in supply chain or other operational disruptions. If we are required to change our current manufacturing partners or suppliers now or in the future in order to avoid such tariffs, the terms of new agreements that we may enter into may not be favorable to us and related operational disruptions may heighten manufacturing and compliance risks. As a result, the continued impact of these tariffs and trade policies may impair our plans for further drug developments for the U.S. market as well as our ability to generate revenues.

Further, we may also be subject to review and enforcement under domestic and foreign laws that screen foreign investment and acquisitions. As a result of these laws, information regarding investments by particular investors may need to be submitted to local regulators, which in turn may impose added costs on our business, impact our operations, and/or limit our ability to engage in strategic transactions that might otherwise be beneficial to us and our investors. These laws are also regularly changed and updated. For example, the U.S. Outbound Investment Security Program restricts direct and indirect investment by U.S. persons into companies with specified connections to China to prevent the transfer of capital and intangible benefits that could be used to accelerate the development of specific technologies of concern. Additional U.S. legislation has been proposed that would further expand the set of technologies of concern. These rules may limit our ability to engage in certain kinds of research or to invest or maintain investments in China, Hong Kong, and Macau and may also limit our ability to raise capital in the U.S. Continuing changes in both U.S. and non-U.S. jurisdictions to foreign investment laws and rules could adversely affect our strategic initiatives, financial performance, and growth prospects.

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

We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, anti-bribery laws in the PRC and possibly other anti-bribery and anti-corruption laws and anti-money laundering laws in countries outside of the United States where we conduct our activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies, their employees, agents, representatives, business partners, and third-party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector.

We sometimes leverage third parties to sell our drug candidates and conduct our business abroad. We, our employees, agents, representatives, business partners and third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third-party intermediaries even if we do not explicitly authorize such activities. We cannot assure you that all of our employees, agents, representatives, business partners or third-party intermediaries will not take actions in violation of applicable law for which we may be ultimately held responsible. As we increase our international sales and business, our risks under these laws may increase.

These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, we cannot assure you that none of our employees, agents, representatives, business partners or third-party intermediaries will take actions in violation of our policies and applicable law, for which we may be ultimately held responsible.

Any allegations or violation of the FCPA or other applicable anti-bribery and anti-corruption laws and anti-money laundering laws could result in whistleblower complaints, sanctions, settlements, prosecution, enforcement actions, fines, damages, adverse media coverage, investigations, loss of export privileges, severe criminal or civil penalties or suspension or debarment from government contracts, all of which could have an adverse effect on our reputation, business, including our financial condition, results of operations and prospects. Responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

Any failure to comply with applicable regulations and industry standards or obtain or maintain various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the United States, and in non-U.S. jurisdictions including the PRC, impose strict rules, regulations and industry standards governing pharmaceutical and biotechnology research and development activities, which apply to us. Our failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, prospects for future work and results of operations. For example, if we were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation, and the accuracy of our animal research data could be questioned.

In addition, we are required to obtain, maintain and renew various permits, licenses and certificates to develop, manufacture, promote, and sell our drug candidates. Third parties, such as distributors, third-party promoters and third-party manufacturers, on whom we may rely to develop, manufacture, promote, sell and distribute our drug candidates may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates. For example, the Regulations on the Administration of Human Genetic Resources, promulgated by the State Council in May 2019 and amended in May 2024, require approval from or filing with the Ministry of Science and Technology of the People's Republic of China where human genetic resources, or HGR, are involved in any international collaborative project and additional approval or filing procedures for any export or cross-border transfer of HGR samples or associated data. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices in relation to our clinical studies, potentially resulting in confiscation of HGR samples and associated data and administrative fines.

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

We and third parties, such as our CROs or contract manufacturing organizations, or CMOs, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. We also store certain low level radioactive waste at our facilities until the materials can be properly disposed of. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Except with respect to our Suzhou facility, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our drug candidates that we commercialize could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from any of our drug candidates that we are able to commercialize (including Olverembatinib and Lisoftoclax). If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our results of operations will be adversely affected. Additionally, if we are unable to generate revenues from sales of Olverembatinib and Lisoftoclax in China or in any jurisdictions for which it received marketing approval or any of our drug candidates that we commercialize, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

We or our CROs, contractors, consultants, or other third parties may suffer system failures, security breaches, or other incidents, which could result in material disruption of our product development programs and adversely impact our business, financial condition or results of operations.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, contractors and consultants who have access to our confidential information.

Despite the implementation of security measures, given the size and complexity of our internal information technology systems and those of our third-party CROs, contractors and consultants and the increasing amounts of confidential information that they maintain, our systems and those of our CROs and other contractors, consultants, and other third parties may be vulnerable to security breaches, and other incidents, including breakdowns or other damage or interruption from system failures, natural disasters, terrorism, war and telecommunication and electrical failures, compromises, disruptions, computer viruses, unauthorized access, cyberattacks and other forms of hacking.

Furthermore, we may be subject to inadvertent or intentional actions by our employees, contractors, consultants and other third parties, or from cyber-attacks by malicious third parties, including the deployment of harmful malware, ransomware, denial-of-service attacks, phishing and other social engineering, and other means to affect reliability and threaten the confidentiality, integrity, and availability of systems or data, which may compromise our or our third-party CROs, contractors or consultants' information technology systems or lead to unauthorized access to, or loss or other processing of, data or other assets, including data that is processed or maintained on our behalf. The risk of a security breach or disruption, particularly through cyberattacks including supply chain attacks such as SolarWinds or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions, including attacks generated by AI, from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as third-party service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such system failure, security breach, or other incident, including any such event that affects our systems or third-party systems where data important to our business operations or commercial development is stored or otherwise processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. If the information technology systems of our third-party CROs, contractors and other consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event and to develop and implement protections to prevent future events of this nature from occurring.

Although to our knowledge we have not experienced any such material system failure, security breach or other incident to date, if such an event were to or be perceived to occur or cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, subject us to financial and reputational harm, compel us to comply with breach notification laws and subject us to mandatory remedial action, which could have a material adverse effect on our business. We cannot assure you that our security measures, or those of our CROs, contractors, consultants or other third parties, have prevented or will prevent such failures, security breaches or other incidents. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Notifications and follow-up actions related to a system failure, security breach or other incident could also impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. We may incur significant costs in an effort to detect and prevent system failures, security breaches, or other incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived system failure, security breach or other incident. We also partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and any similar system failure, security breach or other incident relating to them or affecting their systems or data could also have a material adverse effect on our business. To the extent that we suffer or are perceived to suffer any such failure, security breach, or other incident, including any loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we may also be subject to litigation, investigations, proceedings, and other actions, incur liability and the further development and commercialization of our drug candidates could be delayed, which could have a material adverse effect on our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and commercialization of approved drugs. We face significant risks arising from commercialization of Olverembatinib and Lisoftoclax in China and will face even greater risks arising from future commercialization of it in other markets, including in the United States, and future commercialization of our other drug candidates. For example, we have been involved in and may in the future continue to be involved in, litigation if our drug candidates cause or are perceived to cause or be associated with injury or are found to be otherwise unsuitable during clinical testing, 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 U.S. consumer protection acts and other applicable laws in relevant jurisdictions where we conduct clinical trials or commercialization activities. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize Olverembatinib and Lisoftoclax in the United States or other jurisdictions for which we receive marketing approval or the inability to commercialize any other drug candidate; and
- a decline in the price of our ordinary shares and the ADSs.

Although we have purchased product liability coverage in China and the United States, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. We may seek to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our drug candidates (including Olverembatinib) and Lisoftoclax or any drugs that we in-license, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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 property insurance policies covering physical damage to, or loss of, our buildings and their improvements, equipment, office furniture and inventory. We hold employer's liability insurance generally covering death or work-related injury of employees. We hold public liability insurance covering certain incidents involving third parties that occur on or in the premises of the company. We hold director and officer liability insurance. We do not maintain key-man life insurance on any of our senior management or key personnel, or business interruption insurance. We have some clinical trial related insurance coverage, but it may not cover all situations that may arise relating to a patient who enrolls in our trials. Our insurance coverage may be insufficient to cover certain claims 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.

Changes to existing tax laws, or challenges to our tax positions, could adversely affect our business and financial conditions.

We are subject to income taxes and other taxes in the United States, the PRC and other foreign jurisdictions. Significant judgments and estimates are required in determining our provision for income taxes and other tax liabilities. Our tax expense may be impacted, for example, if tax laws change or are clarified to our detriment or if tax authorities successfully challenge the tax positions that we take, such as, for example, positions relating to the arms-length pricing standards for our intercompany transactions and our state sales and use tax positions.

There is uncertainty regarding future legislative and regulatory changes and policies related to matters such as taxation and importation, and any such proposed or enacted regulations by the current or a future U.S. administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations and operating results.

For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. The One Big Beautiful Bill Act, or OBBBA, reinstates the option to deduct domestic research and development expenditures in the year incurred, commencing with tax years beginning after December 31, 2024. Foreign research and development expenditures remain subject to the 15-year capitalization and amortization requirement. The OBBBA also includes other significant provisions, including tax cut extensions and modifications to the international tax framework. In addition, the IRA, among other things, included a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning in 2023. To the extent that such changes have a negative impact on us, these changes could adversely impact our business, results of operations and financial position.

In determining the adequacy of income taxes, we assess the likelihood of adverse outcomes that could result if our tax positions were challenged by the State Administration of Taxation, or SAT, the Internal Revenue Service, or IRS, and other tax authorities. Should the SAT, the IRS or other tax authorities assess additional taxes as a result of audits or examinations, we may be required to record charges to operations that could adversely affect our business, financial condition and results of operations.

Our global operations and structure subject us to potentially adverse tax consequences.

We generally conduct our global operations through subsidiaries and report our taxable income in various jurisdictions worldwide based on our business operations in those jurisdictions. In particular, our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. Also, our tax expense could be affected depending on the applicability of withholding and other taxes (including withholding and indirect taxes on software licenses and related intercompany transactions) under the tax laws of certain jurisdictions in which we have business operations. The relevant revenue and taxing authorities may disagree with positions we have taken generally, or our determinations as to the value of assets sold or acquired or income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. The tax laws of certain countries in which we do business could also change on a prospective or retroactive basis, and any such changes could increase our liabilities for taxes, interest and penalties, and therefore could harm our business, results of operations and financial condition.

The increasing use of artificial intelligence, or AI, based software (including machine learning) and social media platforms may result in reputation harm or liability or could otherwise adversely affect our business.

AI-based software, including generative AI, is increasingly being used in the biopharmaceutical and global healthcare industries. As with many developing technologies, AI-based software presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. For example, algorithms may be flawed; data sets may be insufficient, of poor quality, or contain biased information or other errors or inadequacies, any of which may not be easily detectable; AI has been known to produce false or “hallucinatory” inferences or outputs; AI can present ethical issues and may subject us to new or heightened legal, regulatory, ethical or other challenges; and inappropriate or controversial data practices by data scientists, engineers, and end-users could impair results. We use AI-based software in our business, and the analyses that AI applications assist in producing may be deficient or inaccurate, which could subject us to competitive harm, potential legal liability, and brand or reputational harm. Furthermore, our use of AI-based software may lead to the inadvertent release of confidential information which may impact our ability to realize the benefit of our intellectual property. If we do not have sufficient rights to use the data or other material or content on which any AI solutions we may use rely, we also may incur liability through the violation of applicable laws, third-party intellectual property, privacy or other rights, or contracts to which we are a party. No assurance can be provided that our use of AI will enhance our business or operations or result in our business or operations being more efficient or profitable.

In addition, regulation of AI is rapidly evolving worldwide as legislators and regulators are increasingly focused on these powerful emerging technologies. The technologies underlying AI and its uses are subject to a variety of laws, including intellectual property, privacy, data protection and cybersecurity, consumer protection, competition, and equal opportunity laws, and are expected to be subject to increased regulation and new laws or new applications of existing laws. While there is currently no comprehensive federal legislation in the U.S. that regulates the development or use of AI, AI is the subject of ongoing review by various U.S. governmental and regulatory agencies, and various U.S. states and other foreign jurisdictions are applying, or are considering applying, their platform moderation, cybersecurity, and data protection laws to AI or are considering general legal frameworks for AI. For example, the significant increase in companies that have incorporated the use of AI in their businesses has increased SEC attention on AI-washing as an area of enforcement. European Union legislators approved the EU Artificial Intelligence Act, or the EU AI Act, which establishes a comprehensive, risk-based governance framework for AI in the EU market. The EU AI Act, and developing interpretation and application of the GDPR in respect of automated decision making, together with developing guidance and/or decisions in the impact of AI technology on data privacy, may affect our use of AI technologies and our ability to provide, improve or commercialize our business, require additional compliance measures and changes to our operations and processes, and result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition.

We may not be able to anticipate how to respond to these rapidly evolving frameworks, and we may need to expend resources to adjust our offerings in certain jurisdictions if the legal frameworks are inconsistent across jurisdictions. Furthermore, because AI technology itself is highly complex and rapidly developing, it is not possible to predict all of the legal, operational or technological risks that may arise relating to the use of AI.

Relatedly, social media platforms are increasingly being used to communicate about our drug candidates and the diseases our drug candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we may fail to monitor and comply with applicable adverse event reporting obligations. There is also a risk of negative or inaccurate posts about us on social media, including criticism regarding our drug candidates. The immediacy of social media precludes us from having real-time control over postings made regarding our Company or drug candidates. Our reputation could be damaged by negative publicity posted on social media platforms which we may not be able to timely reverse. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

We face uncertainties with respect to our leased properties.

We lease real properties from third parties primarily for our offices in China, and the lease agreements for most of these leased properties have not been registered with the PRC government authorities as required by PRC law. We failed to register these lease agreements with relevant housing administrative authorities primarily because the registration of a lease agreement requires cooperation between the lessor and lessee and we have found that lessors are typically unwilling to undertake the administrative burden of registration due to the low risk of penalty. Failure to complete the registration of lease agreements will not affect the validity of the lease agreements or the binding effect of the lease agreements over contracting parties or result in us being required to vacate the leased properties.

Although the failure to do so does not in itself invalidate the leases, we may be ordered by the PRC government authorities to rectify such noncompliance and, if such noncompliance were not rectified within a given period of time, we may be subject to fines imposed by PRC government authorities ranging from RMB1,000 to RMB10,000 for those of our lease agreements that have not been registered with the relevant PRC government authorities. As of the date of this Annual Report on Form 20-F, we are not aware of any regulatory or governmental actions, claims or investigations being contemplated or any challenges by third parties to our use of such leased properties. Moreover, we plan to be more stringent in the future in terms of requiring our lessors to cooperate with us in registering our lease agreements with relevant housing administrative authorities. However, we cannot assure you that the government authorities will not impose fines on us due to our failure to register any of our lease agreements, which may negatively impact our financial condition. Additionally, for some of our leased properties, the owners have not obtained approvals from or made appropriate filings with applicable local authorities, such as drainage permits for the properties. As a result of these non-compliance matters, we may be subject to monetary damages, the suspension or disruption of our operations, interruption of our business, and may be forced to relocate from such properties, which could materially and adversely affect our financial condition and results of operations.

Failure to make adequate contributions to various employee benefit plans as required by PRC regulations or comply with laws and regulations on other employment practices may subject us to penalties.

Companies operating in China are required to participate in various government sponsored employee benefit plans, including certain social insurance, housing funds and other welfare-oriented payment obligations, and contribute to the plans in amounts equal to certain percentages of salaries, including bonuses and allowances, of our employees up to a maximum amount specified by the local government from time to time at locations where we operate our businesses. We cannot assure you that our practices will be deemed to be in compliance with the abovementioned employee benefit plan requirements in all aspects. For example, certain of our PRC subsidiaries engage third-party human resources agencies to make social insurance and housing fund contributions for some of their employees, and there is no assurance that such third-party agencies have made or will make such contributions in a full or in a timely manner. The relevant PRC authorities may require us to pay, or in the case of any shortfalls, to cover, such social insurance and housing fund contributions. We may also become subject to fines and legal sanctions due to any failure to make social insurance and housing fund contributions for our employees. With respect to the underpaid employee benefits, we may be required to complete registrations, make up the contributions for these plans as well as to pay late fees and fines. If we are subject to late fees or fines in relation to the underpaid employee benefits, our financial condition and results of operations may be adversely affected. We may also be subject to regulatory investigations and other penalties if our other employment practices are deemed to be in violation of relevant PRC laws and regulations.

Risks related to doing business in the PRC

We may be subject to further approval, filing or other requirements with PRC governmental authorities in connection with future capital-raising activities.

On July 6, 2021, the General Office of the State Council of the PRC, together with another regulatory authority, jointly promulgated the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law, which calls for 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.

The CSRC and other PRC government authorities have previously implemented new regulations and guidance to regulate overseas listing of domestic enterprises. For instance, on February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Enterprises, or the Provision on Confidentiality, effective on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses documents and materials involving state secrets and working secrets of state organs, or relevant documents and materials, to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses relevant documents and materials through its overseas listing subjects, it shall report to the competent department with the examination and approval authority for approval in accordance with the law, and submit to the secrecy administration department of the same level for filing. For details, see “*Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation—PRC regulations on securities offering and listing outside of China.*” As such regulations relating to overseas listings are newly implemented, there remains substantial uncertainties as to how they may impact our ability to raise or utilize funds overseas and conduct our business operations. Moreover, as the PRC government strengthens the oversight and control over overseas securities offerings and/or foreign investment in China-based issuers, new laws and regulations in relation to overseas listings of China-based issuers may continue to be promulgated and implemented in the future, which may subject us to scrutiny and incur additional compliance costs. We cannot assure you that we will be able to comply with such regulations in a timely and adequate manner or at all. The 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, results of operations and financial condition, as well as the value of the ADSs and ordinary shares. Our failure to meet such requirements could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of our securities to significantly decline or be worthless.

Consequently, if you engage in market trading or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that settlement and delivery may not occur. In addition, if the CSRC or other regulatory authorities later promulgate new rules or explanations requiring that we complete other procedures for future capital raising activities, we may be unable to obtain a waiver of such requirements, if and when procedures are established to obtain such a waiver. Such procedures for obtaining the waiver remain unclear. Any uncertainties or negative publicity regarding such requirements for future capital raising activities could materially and adversely affect our business, prospects, financial condition, reputation and the value of the ADSs and ordinary shares.

Recent greater oversight by the CAC over data security, particularly for companies seeking to list on a foreign exchange, could significantly limit or completely hinder our ability in capital raising activities and materially and adversely affect our business and the value of your investment.

On December 28, 2021, the CAC and several other PRC government authorities jointly promulgated the Cybersecurity Review Measures, which took effect on February 15, 2022 and provides that the relevant operators shall apply with the Cybersecurity Review Office of CAC for a cybersecurity review under certain circumstances such as the purchase of network products and services by “operator of critical information infrastructure,” or CII, or any “online platform operators” controlling personal information of more than one million users which seeks to list in a foreign stock exchange. See “*Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation—PRC regulations on cybersecurity review and data privacy.*” As of the date of this Annual Report on Form 20-F, we have not been informed by any PRC government agency that we qualify as a CII, and we possess personal information of less than one million users. Further, we have not been involved in any cybersecurity-related investigation initiated by the CAC or any other PRC government authority and have not received any cybersecurity-related warning or sanction from the PRC government authorities, or any notice from relevant authorities requesting that we file for the cybersecurity review. Therefore, based on our understanding of the current PRC laws and regulations, as advised by our PRC data compliance counsel JunHe LLP, we are of the view that we are unlikely to be subject to such cybersecurity review arising from our offerings of our securities on a U.S. stock exchange.

On August 20, 2021, the Standing Committee of the National People's Congress, or SCNPC, promulgated the Personal Information Protection Law of the PRC, or the PIPL, which became effective from November 1, 2021, the PIPL illustrates the basic compliance rules of cross-border transfer of personal information. On July 7, 2022, CAC issued the Security Assessment Measures for Data Cross-Border Transfers, which became effective from September 1, 2022. On February 22, 2023, CAC issued the Measures for the Standard Contract for Cross-border Transfer of Personal Information and the Standard Contract for Cross-border Transfer of Personal Information, or the SCC, which became effective from June 1, 2023. On March 22, 2024, the CAC enacted the Provisions on Promoting and Regulating Cross-Border Data Flows. On October 14, 2025, the CAC, together with the SAMR, issued the Measures for Certification of Cross-Border Transfer of Personal Information, which became effective from January 1, 2026. See *"Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation—PRC regulations on cybersecurity and data privacy."* Pursuant to above PRC laws and regulations related to data cross-border transfer, we need to make SCC filing with the local cyberspace administration provincial level or obtain personal information protection certification conducted by professional institutions recognized by CAC for our cross-border transfer of clinical trial subjects' de-identified personal information. As of the date of this Annual Report on Form 20-F, we have completed our SCC filing.

However, it remains uncertain how the existing regulatory measures will be interpreted or implemented in the future, and whether the PRC regulatory agencies, including the CAC, may adopt new laws, regulations, rules, or detailed implementation and interpretation related to the measures, which may have a material adverse effect on our future capital raising activities. If any such new laws, regulations, rules, or implementation and interpretation comes into effect, we face uncertainty as to whether any review or other required actions can be timely completed, or at all.

Given such uncertainty, we may be further required to suspend our business, shut down our platforms or face other penalties, which could materially and adversely affect our business, financial condition and results of operations, or could significantly limit or completely hinder our ability to offer or continue to offer securities to investors, which could cause the value of the ADSs and ordinary shares to significantly decline or become worthless.

If the PCAOB is unable to inspect or investigate completely our auditors located in China because of a position taken by a foreign authority and the SEC identifies the Company as a Commission-Identified Issuer under the Holding Foreign Companies Accountable Act for two consecutive years, the ADSs will be delisted and our ordinary shares and ADSs will be prohibited from trading on a national securities exchange or in the over-the-counter market under the Holding Foreign Companies Accountable Act. The delisting of the ADSs, or the threat of their being delisted, and a prohibition from trading, may materially and adversely affect the value of our ordinary shares.

Pursuant to the Holding Foreign Companies Accountable Act of 2020, or the HFCAA, if the SEC determines that we have filed audit reports issued by a registered public accounting firm that the PCAOB has determined that it is unable to inspect or investigate completely because of an authority in a foreign jurisdiction, it will identify us as a Commission-Identified Issuer. If the SEC determines that we are a Commission-Identified Issuer for two consecutive years, the SEC will prohibit our ordinary shares and ADSs from being traded on a national securities exchange or in the over-the-counter trading market in the United States. Our auditor, Ernst & Young Hua Ming LLP, is an independent registered public accounting firm based in mainland China. On December 2, 2021, the SEC adopted final rules implementing the HFCAA, which include requirements for a Commission-Identified Foreign Issuer to disclose information, including the auditor's name and location, the percentage of shares of the issuer owned by governmental entities and whether governmental entities in the applicable foreign jurisdiction with respect to the auditor has a controlling financial interest with respect to the issuer, among others. These amendments also establish procedures the SEC will follow in identifying issuers and prohibiting trading by certain issuers under the HFCAA.

In August 2022, the PCAOB, the CSRC and the Ministry of Finance of the PRC signed the Statement of Protocol, which establishes a specific and accountable framework for the PCAOB to conduct inspections and investigations of PCAOB-governed accounting firms in mainland China and Hong Kong. On December 15, 2022, the PCAOB announced that it was able to secure complete access to inspect and investigate PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong completely in 2022. The PCAOB Board vacated its previous 2021 determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong. However, whether the PCAOB will continue to be able to satisfactorily access and conduct inspections of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong are subject to uncertainties and depends on a number of factors out of our and our auditor's control. The PCAOB continues to demand complete access in mainland China and Hong Kong moving forward and pursue ongoing investigations and initiate new investigations as needed. The PCAOB has also indicated that it will act immediately to consider the need to issue new determinations with the HFCAA if needed. If the PCAOB determines it is unable to inspect and investigate completely registered public accounting firms located in China for 2023 and beyond, and our registered public accounting firm is located in that jurisdiction, the SEC will identify us as a "Commission-identified Issuer," and upon two consecutive years of non-inspection under the HFCAA, the ADSs will be delisted from Nasdaq and our ordinary shares and ADSs will be prohibited from trading over the counter. We cannot assure you that we would be able to retain a registered public accounting firm that the PCAOB will be able to inspect or investigate completely. Delisting of the ADSs would force holders of the ADSs to sell their ADSs or convert them into our ordinary shares. The foregoing could adversely affect our ability to raise capital. Such a prohibition would also substantially impair your ability to sell or purchase the ADSs when you wish to do so, and the risk and uncertainty associated with delisting would have a negative impact on the price of the ADSs and/or ordinary shares. Moreover, the HFCAA or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of the ADSs could be adversely affected. The prohibition would also significantly affect our ability to raise capital on terms acceptable to us, or at all, which would have a material adverse impact on our business, results of operations and financial condition.

The PCAOB has historically been unable to inspect our auditor in relation to their audit work and the inability of the PCAOB to conduct inspections over our auditor deprives our investors of the benefits of such inspections.

Our auditor, the independent registered public accounting firm that issues the audit report included elsewhere in this Annual Report on Form 20-F, as an auditor of companies that are traded publicly in the United States and 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 is located in China, a jurisdiction where the PCAOB was unable to conduct inspections and investigations before 2022. On December 15, 2022, the PCAOB announced that it was able to secure complete access to inspect and investigate PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong in 2022. However, the inability of the PCAOB to conduct inspections of auditors in China in the past made it more difficult to evaluate the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures as compared to auditors outside of China that have been subject to the PCAOB inspections, which could deprive investors and potential investors in the ADSs of the benefits of such PCAOB inspections, and cause them to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Changes in economic, political or social conditions or government policies from where we operate could have a material adverse effect on our business, results of operations, financial condition, and the value of our securities.

A significant portion of our operations are in the PRC. Accordingly, our business, results of operations and financial condition may be influenced to a significant degree by the political and social conditions in China in general and China's economic growth. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us, leading to a reduction in demand for our drug candidates and adversely affecting our competitive position. Any of the foregoing could result in a material adverse change in our business operations and/or the value of our securities. Our ability to successfully maintain or grow business operations in China depends on various factors, which are beyond our control. These factors include, among others, macro-economic and other market conditions, political stability, social conditions, measures to control inflation or deflation, changes in the rate or method of taxation, changes in laws, regulations and administrative directives or their interpretation, and changes in industry policies. If we fail to take timely and appropriate measures to adapt to any of the changes or challenges, our business, results of operations and financial condition could be materially and adversely affected.

The PRC legal system is evolving, and any failure to comply with laws and regulations could have a material adverse effect on our business, results of operation, financial condition and the value of the ADSs and ordinary shares.

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

Since the late 1970s, the PRC government has promulgated laws and regulations dealing with economic matters, such as foreign investment, corporate organization and governance, commerce taxation and trade, with a view towards developing a comprehensive system of commercial law. For instance, developments in the pharmaceutical industry and other industries and that we are and will be involved in may lead to changes in PRC laws, regulations and policies or in the interpretation and application thereof. As a result, we may be required by the regulators to obtain or renew the licenses, permits, approvals, to complete additional filings or registrations for the products and services we offer, or to modify business practices that may subject us to various penalties, including criminal penalties for individual and entity. We cannot assure you that our business operations would not be deemed to violate any existing or future PRC laws or regulations, which in turn could materially and adversely affect our business operations. In addition, the implementation of new rules, laws and regulations may significantly affect the industry in which we operate, which could affect the value of our securities, such as causing our securities to significantly decline in value or become worthless.

In addition, there is a limited volume of published court decisions due to our civil law system, which may be cited for reference but are not binding on subsequent cases and have limited precedential value unless the Supreme People's Court otherwise provides. The PRC administrative and judicial authorities have certain discretion in interpreting, implementing or enforcing statutory rules and contractual terms, and it may be difficult to precisely predict the outcome of administrative and judicial proceedings. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation.

These evolvments may also affect our decisions on the policies and actions to be taken to comply with PRC laws and regulations, and may affect our ability to enforce contractual rights, property (including intellectual property) or tort rights. In addition, unmerited legal actions or threats in an attempt to extract payments or benefits from us could also happen, which may therefore increase the operating expenses and costs, and materially and adversely affect our business and results of operations.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in the regions where we operate against us or our management named in this Annual Report on Form 20-F based on foreign laws.

A large portion of our operations are conducted in the PRC through our PRC subsidiaries, and a substantial portion of our assets are located in China. We also have senior executive officers who are PRC nationals and reside within China for a significant portion of their time. The courts of mainland China may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law and other applicable laws and regulations based either on treaties between mainland China and the country or the region where the judgment is made or on principles of reciprocity between jurisdictions. However, China does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts with the Cayman Islands and many other countries and regions. Even if you are successful in bringing an action of this kind, PRC laws may render you unable to enforce a judgment against our assets or the assets of our directors and officers if such enforcement is not in compliance with relevant PRC laws and regulations.

It may be difficult for overseas regulators to conduct investigation or collect evidence within the regions where we operate.

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 instance, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigations initiated outside of 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 United States may not be efficient in the absence of mutual and practical cooperation mechanism. 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. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no organization or individual may provide the documents and materials relating to securities business activities to overseas parties, which could present significant legal and other obstacles to obtaining information needed for investigations and litigation conducted outside of China. The Provisions on Strengthening the Confidentiality and Archives Administration Related to the Overseas Securities Offering and Listing by Domestic Enterprises, which became effective on March 31, 2023, provides that the investigation and evidence collection in relation to the overseas securities offering and listing of the PRC domestic companies by the overseas securities regulatory authorities and relevant authorities shall be conducted through the cross-border cooperation mechanism for supervision and administration and the domestic companies in mainland China shall obtain the prior consent from the CSRC or relevant authorities before cooperating with such overseas securities regulatory authorities or relevant authorities in connection with relevant inspections or investigations or providing relevant documents to such overseas securities regulatory authorities or relevant authorities. The inability for 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. If the U.S. securities regulatory agencies are unable to conduct such investigations, there exists a risk that they may determine to suspend or de-register our registration with the SEC and may also delist our securities from trading market within the United States.

Litigation and negative publicity surrounding China-based companies listed in the United States may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs.

We believe that litigation and negative publicity surrounding companies with operations in China that are listed in the United States have negatively impacted stock prices for such 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 published reports on China-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and listing suspensions on U.S. national exchanges. Any similar scrutiny of 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 tension in international trade, rising political tension and increasing geopolitical risks, particularly between the United States and China, pose significant challenges that may adversely impact our business, results of operations and financial condition.

Our business could be materially and adversely affected by the tensions in international trade in recent years. Changes to international trade policies, laws, regulations and administrative orders could adversely affect the global economic conditions. In addition, geopolitical tensions among major economies have escalated due to, among other things, trade disputes, global health emergencies, sanctions imposed by the U.S. Department of Treasury, and the executive orders issued by the U.S. government that may prohibit transactions with certain selected Chinese companies as well as their products and services. Rising political tensions could reduce levels of trade, investment, technological exchange and other economic activities between the two major economies, or result in new tariffs, sanctions, export controls, or other new laws and regulations. The recent retaliatory tariff increases between the U.S. and China in April 2025 may result in significantly escalating tensions between the two countries. Such tensions involving China, and any escalation thereof, may negatively affect trading and business environments, which may, in turn, adversely impacting our business, results of operations and financial condition.

When it comes to our industry in particular, certain Chinese biotechnology companies and CMOs may become subject to legislation, trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the BIOSECURE Act was signed into law on December 18, 2025, and it targets U.S. government contracts, grants, and loans for entities that use equipment and services from Chinese biotechnology companies of concern. Though the BIOSECURE Act does not name WuXi as a ‘company of concern’, such a designation is still under consideration by other governmental departments. We contract with WuXi STA, a subsidiary of WuXi AppTec, that manufactures certain of our active pharmaceutical ingredients. In addition, U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties’ lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. If any other current or future supplier is included under or otherwise added to the BIOSECURE Act or otherwise designated on any U.S. government prohibited party lists, such designation could impact and potentially restrict our engagement with such suppliers. While we believe that our current manufacturing plan will provide us with alternative sources for such supplies, there is a risk that, if supplies are interrupted, or the quality of ingredients provided by such alternative sources is not to our specification, it would cause delays in our supply chain and increase the cost of manufacturing our drugs and/or drug candidates, which could materially harm our business.

Further regulatory changes limiting trade with China could affect our research and development activities or business operations, including, for example, in 2024, Congress passed H.B. 815, which included the Protecting Americans’ Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive U.S. data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business. In addition, the political landscape in the United States has affected U.S. government’s attitude towards China and may increase the likelihood of the imposition of further restrictions on biopharmaceutical companies that have substantial operations in China, in particular under the current U.S. administration. Companies with substantial operations in China may have to limit and reduce their research and development and other business activities, or cease conducting transactions with parties, in the United States and other countries that impose export controls or other restrictions. Given our substantial research and development activities in the United States and China and our cooperation with certain U.S.-and China-based suppliers, our business is particularly susceptible to these controls and restrictions, and our financial condition and results of operations could be materially and adversely affected as a result.

Payment of dividends is subject to restrictions under the PRC law. 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.

Ascentage Pharma Group International is a Cayman Islands exempted company, and its ability to declare future dividends will depend on the availability of dividends, if any, received from our PRC subsidiaries. Under PRC laws and regulations, each of our PRC subsidiaries may pay dividends only out of its respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. For a detailed discussion of applicable PRC regulations governing distribution of dividends, see “Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation—PRC regulations relating to dividend distribution.” As a result of these laws, rules and regulations, our PRC subsidiaries are restricted in their ability to transfer a portion of their respective net assets to their shareholders as dividends. Furthermore, if our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing their debt may restrict their ability to pay dividends or make other distributions to us.

While there are currently no such restrictions on foreign exchange and our ability to transfer cash or assets between Ascentage Pharma Group International and our Hong Kong subsidiaries, if certain PRC laws and regulations, including existing laws and regulations and those enacted or promulgated in the future were to become applicable to our Hong Kong subsidiaries in the future, and to the extent our cash or assets are in Hong Kong or a Hong Kong entity, such funds or assets may not be available due to interventions in or the imposition of restrictions and limitations on our ability to transfer funds or assets by the PRC government. Furthermore, we cannot assure you that the PRC government will not intervene or impose restrictions on Ascentage Pharma Group International, its subsidiaries and the affiliated entities to transfer or distribute cash within the organization, which could result in an inability of or prohibition on making transfers or distributions to entities outside of mainland China and Hong Kong.

In addition, the Enterprise Income Tax Law 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.

Any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their Renminbi revenues to pay dividends to us. 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 or make investments that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

Governmental regulations of currency conversion may limit our ability to pay dividends and other obligations and affect the value of our ordinary shares.

The PRC government imposes regulations on the convertibility of Renminbi into foreign currencies and the remittance of funds out of China. A significant portion of our revenue is in RMB. We may convert a portion of our revenue into other currencies to meet our foreign currency obligations, such as payments of dividends declared in respect of the ADSs, if any. Shortages in the availability of foreign currency may affect 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 denominated obligations.

Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments, and trade and service-related foreign exchange transactions, can be made in foreign currencies without the prior approval of PRC State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. However, approval from or registration or filings with competent government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. Pursuant to the Circular on Reforming the Management Approach regarding the Foreign Exchange Capital Settlement of Foreign-invested Enterprise, or the SAFE Circular 19, a foreign-invested enterprise may convert up to 100% of the foreign currency in its capital account into Renminbi on a discretionary basis according to the actual needs. The Circular on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts, or the SAFE Circular 16, provides for an integrated standard for conversion of foreign exchange under capital account items on a discretionary basis, which applies to all enterprises registered in China. In addition, the SAFE Circular 16 has narrowed the scope of purposes for which an enterprise must not use the Renminbi funds so converted, which include, among others, (1) directly or indirectly used for payments for expenditure beyond its business scope or otherwise as prohibited by the applicable laws and regulations, (2) unless otherwise expressly provided, directly or indirectly used for investment in securities or other financial products (except for financial products with risk ratings not higher than Level 2 and structured deposits), (3) provision of loans to non-affiliated enterprises, except where it is expressly permitted in the business scope of the enterprise and (4) construction or purchase of real properties for use by third parties, except for enterprises engaging in real estate development and real estate leasing. We cannot assure you that additional restrictions on the convertibility of the RMB into foreign currencies for current account transactions will not be imposed in the future. If we cannot obtain sufficient foreign currencies to satisfy our foreign currency needs, we may not be able to pay dividends in foreign currencies to our shareholders. Further, we cannot assure you that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

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

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the M&A Rules, and some other regulations and rules concerning mergers and acquisitions established complex procedures and requirements for the acquisition of Chinese companies by foreign investors, including requirements in some instances that the Ministry of Commerce of the PRC, or MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise. Moreover, the Anti-monopoly Law promulgated by the SCNPC requires that transactions which are deemed concentrations and involve parties with specified turnover thresholds must be cleared by the anti-monopoly enforcement agency before they can be completed. In addition, the Measures for the Security Review of Foreign Investment promulgated by the NDRC and MOFCOM in December 2020 specify that foreign investments in the military, national defense-related areas or in locations in proximity to military facilities, or foreign investments that would result in acquiring the actual control of assets in certain key sectors, such as critical agricultural products, energy and resources, equipment manufacturing, infrastructure, transport, cultural products and services, information technology, internet products and services, financial services and technology sectors, are required to obtain approval from designated government authorities in advance.

In the future, we may pursue potential strategic acquisitions that are complementary to our business. Complying with the requirements of the above-mentioned regulations and other rules to complete such transactions could be time-consuming, and any required approval processes may delay or inhibit our ability to complete such transactions, which could affect our ability to expand business or maintain market share. Furthermore, there is a possibility that the PRC regulators may promulgate new rules or explanations requiring that we obtain the approval of MOFCOM or other PRC government authorities for our mergers and acquisitions. We cannot assure you that we can obtain such approval from MOFCOM or any other relevant PRC government authorities for our mergers and acquisitions. Any uncertainties regarding such approval requirements could have a material adverse effect on our business and results of operations and our corporate structure.

PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of our public and private financings to make loans to or make additional capital contributions to our PRC subsidiaries, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

Any funds we transfer to our PRC subsidiaries, either as a shareholder loan or as an increase in registered capital, are subject to approval by or registration with relevant governmental authorities in China. According to the relevant PRC regulations on foreign-invested enterprises in China, capital contributions to our PRC subsidiaries are subject to registration with the State Administration for Market Regulation or its local counterpart and registration with a local bank authorized by SAFE. In addition, (1) any foreign loan procured by our PRC subsidiaries is required to be registered with SAFE or its local branches and (2) any of our PRC subsidiaries may not procure loans that exceed the difference between its total investment amount and registered capital or, as an alternative, they may only procure loans subject to the calculation approach and limitation as provided by the People's Bank of China. SAFE promulgated the SAFE Circular 19, effective from June 2015, in replacement of a former regulation. According to SAFE Circular 19, the flow and use of the Renminbi capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise is regulated such that Renminbi capital may not be used for the issuance of Renminbi entrusted loans, the repayment of inter-enterprise loans or the repayment of bank loans that have been transferred to a third party. Although SAFE Circular 19 allows Renminbi capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise to be used for equity investments within China, it also reiterates the principle that Renminbi converted from the foreign currency-denominated capital of a foreign-invested company may not be directly or indirectly used for purposes beyond its business scope. Thus, it is unclear whether SAFE will permit such capital to be used for equity investments in China in actual practice. SAFE promulgated the SAFE Circular 16, effective from June 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using Renminbi capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue Renminbi entrusted loans to a prohibition against using such capital to issue loans to non-associated enterprises. Violations of SAFE Circular 19 and SAFE Circular 16 could result in administrative penalties. The SAFE Circular 19 and SAFE Circular 16 may significantly limit our ability to transfer any foreign currency we hold, including the net proceeds from our public and private financings, to our PRC subsidiaries, which may adversely affect our liquidity and our ability to fund and expand our business in China. On October 23, 2019, SAFE promulgated the Circular of Further Facilitating Cross-border Trade and Investment, or the SAFE Circular 28, which, among other things, allows all foreign-invested enterprises to use Renminbi converted from foreign currency-denominated capital for equity investments in China, as long as the equity investment is genuine, does not violate applicable laws, and complies with the negative list on foreign investment. On April 10, 2020, the SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business, or the SAFE Circular 8, under which eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing without providing the evidentiary materials concerning authenticity of each expenditure in advance, provided that their capital use shall be authentic and conforms to the prevailing administrative regulations on the use of income under capital accounts. On December 4, 2023, SAFE issued the Notice on Further Deepening the Reform to Facilitate Cross-border Trade and Investment, which releases new foreign exchange management policies and revises some rules under SAFE Circular 16 and SAFE Circular 28.

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, or at all, with respect to future loans or capital contributions by us to our PRC subsidiaries. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds from our public and private financings and to capitalize or otherwise fund the PRC operations may be negatively affected, which could materially and adversely affect our liquidity and the ability to fund and expand our business.

Failure to comply with PRC regulations relating to the establishment of offshore special purpose companies by PRC residents may subject our PRC resident beneficial owners or our PRC subsidiaries to liability or penalties, limit our ability to inject capital into our PRC subsidiaries, limit our PRC subsidiaries' ability to increase its registered capital or distribute profits to us, or may otherwise adversely affect us.

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles, or the SAFE Circular 37, in July 2014. SAFE Circular 37 requires PRC residents or entities to register with SAFE or its local branch in connection with their establishment or control of an offshore entity established for the purpose of overseas investment or financing with such PRC residents or entities' legally owned assets or equity interests in domestic enterprises or offshore assets or interests. On February 13, 2015, SAFE issued the Circular on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, or the SAFE Circular 13, effective on June 1, 2015, pursuant to which the power to accept SAFE registration was delegated from local SAFE to local qualified banks where the assets or interest in the domestic entity was located. In addition, such PRC residents or entities must update their SAFE registrations when the offshore special purpose vehicle undergoes material events relating to any change of basic information (including change of such PRC citizens or residents, name and operation term), increases or decreases in investment amount, transfers or exchanges of shares, or mergers or divisions.

If our shareholders who are PRC residents or entities do not complete their registration with the local SAFE branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restrictions. In addition, our shareholders who are PRC entities shall complete their overseas direct investment filings according to applicable laws and regulations regarding overseas direct investment by PRC entities, including filings with MOFCOM, the NDRC, or their local branches based on the amount and industry of the investments or other factors thereof.

We have used our best efforts to notify PRC residents or entities who directly or indirectly hold shares in our Cayman Islands exempted company and who are known to us as being PRC residents or entities to complete the foreign exchange registrations or overseas direct investment filings. However, we may not at all times be fully aware or informed of the identities of all the PRC residents or entities holding direct or indirect interest in our Company, nor can we compel our beneficial owners to comply with SAFE registration requirements. We also cannot assure you that all shareholders or beneficial owners of ours who are PRC residents or entities will in the future make, obtain or update any applicable registrations, filings or approvals required by SAFE regulations or other regulations relating to overseas investment activities issued by MOFCOM and NDRC. Failure by such shareholders or beneficial owners to comply with such regulations, or failure by us to amend the foreign exchange registrations of our PRC subsidiaries, could subject us to fines or legal sanctions, restrict our overseas or cross-border investment activities, limit our PRC subsidiaries' ability to make distributions or pay dividends to us or affect our ownership structure, which could adversely affect our business, results of operations and financial condition.

If we fail to comply with PRC regulations regarding the registration requirements for employee equity incentive plans or share option plans, the PRC plan participants or we could be subject to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, or the SAFE Circular 7. Pursuant to SAFE Circular 7, directors, supervisors, senior management and other employees participating in any stock incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiary of such overseas-listed company, and complete certain other procedures, unless certain exceptions are available. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. We and our executive officers and other employees who are PRC citizens or non-PRC citizens living in China for a continuous period of not less than one year and have been granted options are subject to these regulations as our Company has become an overseas-listed company. Failure to complete SAFE registrations may subject them to fines of up to RMB50,000 for individuals and may also limit our ability to contribute additional capital to our PRC subsidiaries and our PRC subsidiaries' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers, and employees under PRC law. See “Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation.”

In addition, the Ministry of Finance and the State Administration of Taxation, or the SAT, have issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiaries have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees who exercise their share options or are granted restricted shares. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

If we are classified as a PRC resident enterprise for PRC tax purposes under the EIT Law, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with a “de facto management body” within China is considered a “resident enterprise” and will be subject to the enterprise income tax on its global income at the rate of 25%. 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 2009, the SAT issued the Circular on Issues Concerning the Determination of Chinese-Controlled Enterprises Registered Overseas as Resident Enterprises on the Basis of Their Bodies of Actual Management, or the 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 like us, the 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 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 and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met: (1) the primary location of the day-to-day operational management is in China; (2) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in China; (3) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (4) at least 50% of voting board members or senior executives habitually reside in China.

We believe none of our entities outside of China is a PRC resident enterprise for PRC tax purposes. 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.” If the PRC tax authorities determine that our Cayman Islands exempted company is a resident enterprise for PRC EIT purposes, a number of unfavorable PRC tax consequences could follow and we may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to PRC EIT reporting obligations. In addition, non-resident enterprise shareholders (including the ADS holders) will be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of, or dividends paid on, the ADSs or ordinary shares (which in the case of dividends will be withheld at source) if such gain or income is treated as sourced from within China. 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 our ordinary shares by such shareholders may be subject to PRC tax at a rate of 20% (which in the case of dividends will be withheld at source) unless a reduced rate is available under an applicable tax treaty. It is unclear whether non-PRC shareholders (including ADS holders) of our Company would be able to obtain 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. Any such tax may reduce the returns on your investment in the ADSs.

In addition to the uncertainty as to the application of the “resident enterprise” classification, we cannot assure you that the PRC government will not amend or revise the taxation laws, rules and regulations to impose stricter tax requirements or higher tax rates. Any of such changes could materially and adversely affect our business, results of operations and financial condition.

We face uncertainties with respect to the indirect transfers of equity interests in PRC resident enterprises by their non-PRC holding companies.

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax on Indirect Transfers of Assets by Non-PRC Resident Enterprises, or the SAT Bulletin 7. SAT Bulletin 7 applies to transactions through offshore transfer by a foreign company directly or indirectly holding taxable assets in China. In addition, SAT Bulletin 7 provides certain criteria on how to assess reasonable commercial purposes and has introduced safe harbors for internal group restructurings and the purchase and sale of equity through a public securities market. SAT Bulletin 7 also brings challenges to both the foreign transferor and transferee (or other person who is obligated to pay for the transfer) of taxable assets. On October 17, 2017, the SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or the SAT Bulletin 37, which came into effect on December 1, 2017. SAT Bulletin 37 further clarifies the practice and procedure of the withholding of non-resident enterprise income tax.

Where a non-resident enterprise transfers taxable assets indirectly by disposing of the equity interests of an overseas holding company, which is an indirect transfer, the non-resident enterprise as either transferor or transferee, or the PRC entity that directly owns the taxable assets, may report such indirect transfer to the relevant tax authority. 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.

We 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, and sale of the shares in our offshore subsidiaries and investments. For transfer of shares in our Company by investors who are non-PRC resident enterprises, our PRC subsidiaries may be requested to assist in the filing under SAT Bulletin 7 and/or SAT Bulletin 37. As a result, we may be required to expend valuable resources to comply with SAT Bulletin 7 and/or SAT Bulletin 37, or to establish that we and our non-PRC resident investors should not be taxed under these circulars, which may have a material and adverse effect on our business, results of operations and financial condition.

The custodians or authorized users of our controlling non-tangible assets, including chops and seals, may fail to fulfill their responsibilities or misappropriate or misuse these assets.

Under PRC laws, legal documents for corporate transactions are executed using the chop or seal of the signing entity or with the signature of a legal representative whose designation is registered and filed with the relevant branch of the State Administration for Market Regulation, or the SAMR. Although we usually utilize chops to enter into contracts, the designated legal representatives of our PRC subsidiaries have the apparent authority to enter into binding contracts on behalf of these entities without chops. In order to maintain the physical security of our chops, we generally have them stored in secure locations accessible only to authorized employees. Although we monitor such authorized employees, the procedures may not be sufficient to prevent all instances of abuse or negligence. There is a risk that our employees could abuse their authority, for instance, by entering into a contract not approved by us, or seeking to gain control of any of our subsidiaries. If any employee obtains, misuses or misappropriates corporate chops and seals or other controlling non-tangible assets for whatever reason, the business operations of the relevant entities could be disrupted. We may have to take corporate or legal action to seek the return of the chops, apply for new chops with the relevant authorities, or otherwise seek legal redress for the violation of the representative’s fiduciary duties against us, which could involve significant time and resources to resolve and divert management attention from business operations. In addition, the affected entity may not be able to recover corporate assets that are sold or transferred out of our control in the event of such a misappropriation if a transferee relies on the apparent authority of the representative and acts in good faith.

Fluctuations in exchange rates could have a material adverse effect on our results of operations and the value of your investment.

The conversion of Renminbi into foreign currencies, including the U.S. dollar, is based on rates set by the People’s Bank of China. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in China’s political and economic conditions and by China’s foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the U.S. dollar and other currencies in the future. It is difficult to predict how market forces or PRC, or U.S. government policy may impact the exchange rate between Renminbi and U.S. dollar in the future.

We incur portions of our expenses, and may in the future derive revenues, in currencies other than the RMB, in particular, the U.S. dollar. Any significant appreciation or depreciation of Renminbi may materially and adversely affect our revenues, earnings and financial condition, and the value of, and any dividends payable on, the ADSs in U.S. dollars. For example, a significant portion of our clinical trial activities are conducted outside of the PRC, and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in currency exchange rates. A decline in the value of the RMB against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs. Furthermore, to the extent that we need to convert U.S. dollars we receive into Renminbi to pay our operating expenses, appreciation of Renminbi against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, a significant depreciation of RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our earnings, which in turn could adversely affect the price of the ADSs.

We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the RMB. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited, and we may not be able to adequately hedge our exposure, or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert Renminbi into foreign currency.

Risks related to our ordinary shares and the ADSs

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs and ordinary shares.

The ADSs are listed on the Nasdaq Global Market, and our ordinary shares are listed on the HKEx. Trading of the ADSs or ordinary shares in these markets takes place in different currencies (U.S. dollars on Nasdaq and HK\$ on the HKEx), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Hong Kong). The trading prices of our ordinary shares and the ADSs representing them may differ due to these and other factors, even allowing for currency differences. Any decrease in the price of our ordinary shares on the HKEx could cause a decrease in the trading price of the ADSs on Nasdaq. Fluctuations in the price of ordinary shares due to circumstances peculiar to the HKEx could materially and adversely affect the price of the ADSs. Because of the different characteristics of the U.S. and Hong Kong equity markets, the historic market prices of our ordinary shares may not be indicative of the performance of the ADSs.

Investors could seek to sell or buy our ordinary shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both the ADSs on Nasdaq and the ordinary shares available for trading on the HKEx. In addition, holders of ADSs will not be immediately able to surrender their ADSs and withdraw the underlying ordinary shares for trading on the other market without effecting necessary procedures with the depository. See “—*The time required for the exchange between our ordinary shares and ADSs might be longer than expected and investors might not be able to settle or effect any sale of their securities during this period, and the exchange between our ordinary shares and ADSs involves costs.*” This could result in time delays and additional cost for holders of ADSs. We cannot predict the effect of this dual listing on the value of our ordinary shares and the ADSs. However, the dual listing of our ordinary shares and the ADSs may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States.

The trading prices of the ADSs are likely to be volatile, which could result in substantial losses to you.

The price and trading volume of the ADSs may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. Our share price in Hong Kong has fluctuated from a 52-week high of HK\$95.35 to a low of HK\$38.15, and our price of our ADSs has fluctuated from a 52-week high of \$48.45 to a low of \$19.11, each as of April 22, 2026. In addition, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of the ADSs. In addition to market and industry factors, the price and trading volume of the ADSs may be highly volatile for specific business reasons, such as fluctuations in our revenue, earnings, cash flows, investments, expenditures, regulatory developments, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors.

In addition to market and industry factors, the price and trading volume for the ADSs may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to acquire or license additional drug candidates;
- variations in the level of expenses related to our existing drug candidates or preclinical and clinical development programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- variations in our results of operations;
- announcements about our earnings that are not in line with analyst expectations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- press reports, whether or not true, about our business;
- additions to or departures of our management;
- fluctuations of exchange rates between the RMB, the U.S. dollar and other currencies;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs;
- sales or perceived potential sales of additional ordinary shares or ADSs;
- sales of our ordinary shares or ADSs by us, our executive officers and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. and Hong Kong equity markets;
- changes in accounting principles; and
- changes or developments in the PRC or global regulatory environment.

Any of these factors may result in large and sudden changes in the volume and trading price of the ADSs. In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of management, and, if adversely determined, have a material adverse effect on our financial condition and results of operations.

In addition, the stock market, in general, and small pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of the ADSs, regardless of our actual operating performance and may cause the price of the ADSs to decline rapidly and unexpectedly.

The time required for the exchange between our ordinary shares and ADSs might be longer than expected and investors might not be able to settle or effect any sale of their securities during this period, and the exchange between our ordinary shares and ADSs involves costs.

There is no direct trading or settlement between Nasdaq and the HKEx. In addition, the time differences between New York and Hong Kong, unforeseen market circumstances, or other factors may delay the deposit of ordinary shares in exchange for the ADSs or the withdrawal of ordinary shares underlying the ADSs. Investors will be prevented from settling or effecting the sale of their securities during such periods of delay. In addition, we cannot assure you that any exchange for ordinary shares into ADSs (and vice versa) will be completed in accordance with the timelines that investors may anticipate.

Furthermore, the depository for the ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. As a result, shareholders who exchange ordinary shares into ADSs, and vice versa, may not achieve the level of economic return the shareholders may anticipate.

Substantial future sales or perceived potential sales of the ADSs, ordinary shares or other equity securities in the public market could cause the price of the ADSs to decline significantly.

Sales of substantial amounts of the ADSs in the public market, or the perception that these sales could occur, could adversely affect the market price of the ADSs and could materially impair our ability to raise capital through equity offerings in the future. The ADSs are freely tradable without restriction or further registration under the Securities Act, and all other ordinary shares held by our existing shareholders may also be sold in the public market in the future, subject in certain cases to the restrictions in Rule 144 and Rule 701 under the Securities Act. As of April 1, 2026, there are 928,218 ADSs, representing 3,712,872 ordinary shares, or 1% of our outstanding ordinary shares. We have registered the offer and sale of all shares of ordinary shares that we may issue under our equity compensation plans. Ordinary shares issued under our equity compensation plans as a result of the exercise of stock options or vesting of RSUs outstanding under our equity compensation plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 under the Securities Act. 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 and our ordinary shares.

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

The ADSs are transferable on the books of the depository. However, the depository may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depository may close its books from time to time for a number of reasons, including in connection with corporate events, such as a rights offering, or "for record date or processing purposes" in emergencies, and on weekends and public holidays. The depository may refuse to deliver, transfer or register transfers of the ADSs generally when our share register or the books of the depository are closed, or at any time if we or the depository 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.

If a United States person is treated as owning at least 10% of our share capital, such person may be subject to adverse U.S. federal income tax consequences.

If a United States person, as defined by the Internal Revenue Code of 1986, as amended, is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our share capital, such person may be treated as a “United States shareholder” with respect to each non-U.S. corporation in our group that is a “controlled foreign corporation,” or CFC, for U.S. federal income tax purposes. A non-U.S. corporation will be a CFC if United States shareholders, as defined in the immediately preceding sentence, own directly, indirectly or constructively (through attribution), more than 50% of either the total combined voting power or total value of the stock of such corporation. No assurances can be provided that we are not a CFC or will not be a CFC. A United States shareholder that owns our ordinary shares or ADSs directly or indirectly may be required to report annually and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by our subsidiary CFCs, regardless of whether we make any distributions. Failure to comply with such reporting requirements could result in adverse tax effects for United States shareholders and potentially significant monetary penalties. We do not currently expect to assist investors in determining whether we or any of our non-U.S. subsidiaries is treated as a CFC or furnish to any United States shareholders information that may be necessary to comply with the aforementioned obligations. A United States investor should consult its advisors regarding the potential application of these rules to an investment in the ADSs.

We previously identified a material weakness in our internal control over financial reporting in connection with the audit of our financial statements as of and for the years ended December 31, 2022 and 2023, which has been remediated. We may identify additional material weaknesses in the future. If we fail to maintain an effective system of internal controls over financial reporting in the future, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence and the market price of the ADSs may be materially and adversely affected.

As defined in the standards established by the PCAOB, a “material weakness” is a deficiency, or a combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

As a public company with securities traded in the United States, we are subject to reporting obligations under the U.S. securities laws, including the Sarbanes-Oxley Act of 2002. Section 404(a) of the Sarbanes-Oxley Act requires that management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting.

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. 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 a report that is qualified 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, as a public company, 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 of the Sarbanes-Oxley Act, we may identify 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 of the Sarbanes-Oxley Act and we may not be able to meet our reporting obligations, avoid material misstatements in our financial statements or comply with applicable financial reporting requirements and related regulatory filings on a timely basis. 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. As a result, our business, financial condition, results of operations and prospects, as well as the trading price of our ADSs, may be materially and adversely affected.

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

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 interest for the price of the security 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 security short. These short attacks have, in the past, led to selling of shares in the market.

Public companies listed in the United States that have a substantial majority 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.

We may be the subject of unfavorable allegations made by short sellers in the future. Any such allegations may be followed by periods of instability in the market price of our ordinary shares and ADSs and negative publicity. If and when we become the subject of any unfavorable allegations, whether such allegations are proven to be true or untrue, we could have to expend a 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 we can proceed against the relevant short seller by principles of freedom of speech, applicable federal or 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 and shareholders' equity, and the value of any investment in the ADSs could be greatly reduced or rendered worthless.

We have broad discretion in the use of the net proceeds from our public and private financings and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this Annual Report on Form 20-F titled "Use of proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. We currently anticipate that we will use the net proceeds from our public and private financings, together with our existing cash and cash equivalents and our loan facility, as follows: (1) to fund the research and development of Olverembatinib, including activities related to the various registrational trials and other clinical trials, as well as pursuing approvals with regulatory authorities in multiple countries; (2) to fund the research and development of Lisaftoclax, including activities related to the various registrational trials and other clinical trials, as well as pursuing approvals with regulatory authorities in multiple countries; and (3) to fund the research and development of our other product candidates, and strengthen our technology platforms and research and development capabilities. We intend to use any remaining net proceeds for working capital and general corporate purposes. Because of the number and variability of factors that will determine our use of the net proceeds from our public and private financings, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these proceeds effectively could adversely affect our business, financial condition and results of operations. Pending their use, we may invest our net proceeds in a manner that does not produce income or that loses value. Our investments may not yield a favorable return to our investors and may negatively impact the price of the ADSs.

Insiders will continue to have significant influence over us, and their interests may not be aligned with the interest of our other shareholders.

As of April 20, 2026, our directors, executive officers, holders of more than 5% of our ordinary shares and their respective affiliates beneficially own, in the aggregate, approximately 22.56% of our outstanding ordinary shares. Our co-founders — Dr. Yang, our Chairman and Chief Executive Officer, Dr. Zhai, our Chief Medical Officer, Dr. Wang, a member of our board of directors and Dr. Guo — and their respective affiliates who beneficially own approximately 15.9% of our outstanding ordinary shares as of April 20, 2026, are parties to the Concert Party Confirmation Deed, or the Deed, pursuant to which such parties, amongst other things, agreed to actively cooperate and communicate with each other to obtain and maintain consolidated control and management of our Company and agreed to vote unanimously as a group on all matters and resolutions proposed at shareholder meetings of our Company. See “Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert party confirmation deed.” As a result of such ownership and the Deed, such insiders, and in particular our co-founders, will, through their voting power at our shareholder meetings and their delegates on our board of directors, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments and our management. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be adverse to your interests. In addition, without the consent of such shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our shareholders of an opportunity to receive a premium for the shares as part of a sale of our company and may significantly reduce the price of the ADSs.

There can be no assurance that we will not be a passive foreign investment company, or PFIC, for United States federal income tax purposes for any taxable year, which could subject United States investors in the ADSs or ordinary shares to significant adverse United States income tax consequences.

A non-U.S. corporation, such as our Company, will be classified as a “passive foreign investment company”, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (1) 75% or more of its gross income for such year consists of certain types of “passive” income, the “income test,” or (2) 50% or more of the amount of its assets (generally determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income, the “asset test.” For this purpose, cash and assets readily convertible into cash are categorized as passive assets, and the Company’s goodwill and other unbooked intangibles are taken into account. Passive income generally includes, among other things, dividends, interest, rents, royalties (other than certain royalties treated as derived in an active conduct of a trade or business), and gains from the disposition of passive assets. We will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, at least 25% (by value) of the stock.

For purposes of the PFIC asset test, the amount of our assets will generally be determined by reference to their value, which may be determined by reference to our market capitalization. However, if we are considered to be a CFC that is not “publicly traded” for purposes of the PFIC rules during the tested period, the amount of our assets will generally be determined by reference to our adjusted bases in our assets. Further, for purposes of applying the PFIC asset test to us, if any entity in which we own 25% or more of the total value of the outstanding shares of such entity is considered to be a CFC that is not publicly traded, the amount of such entity’s assets would generally be determined by reference to its adjusted bases in its assets. No assurances can be provided that we or any of our subsidiaries are not a CFC or will not be a CFC, and consequently, no assurances can be given that the PFIC asset test will not be applied to us based on the adjusted bases of our non-U.S. subsidiaries in their assets.

Provided that we and our subsidiaries were not, and do not become, CFCs, based on the composition of our income and assets and the estimated value of our assets, which is based on our current market capitalization, we do not presently expect to be a PFIC for our current fiscal year or future fiscal years. However, no assurance can be given that we will not be a PFIC for the current fiscal year or future fiscal years because the determination of whether we will be or become a PFIC for any taxable year is a fact intensive determination made annually after the close of each taxable year that depends, in part, upon the composition and classification of our income and assets. Fluctuations in the market price of the ADSs may cause us to be or become classified as a PFIC for the current or future fiscal years because the value of our assets for purposes of the asset test, including the value of our goodwill and unbooked intangibles, may be determined by reference to the market price of the shares or ADSs from time to time (which may be volatile). Among other matters, if our market capitalization is less than anticipated or subsequently declines, we may be or become classified as a PFIC for the current fiscal year or future fiscal years.

If we are a PFIC for any taxable year during which a U.S. Holder (as defined in the section of this Annual Report on Form 20-F titled “Item 10. Additional Information—E. Taxation—U.S. federal income tax considerations—General”) holds an ADS or an ordinary share, certain adverse U.S. federal income tax consequences could apply to the U.S. Holder. See the section of this Annual Report on Form 20-F titled “Item 10. Additional Information—E. Taxation—U.S. federal income tax considerations—Passive foreign investment company rules.”

Our second amended and restated 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 second amended and restated memorandum and articles of association contain provisions which could limit the ability of others to acquire control of our Company or cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders and ADS holders of an opportunity to sell their shares or ADSs at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our Company in a tender offer or similar transactions. Our board of directors has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix their designations, powers, preferences, privileges, and relative participating, optional or special rights and the qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares, in the form of ADS or otherwise. Preferred shares could be issued quickly with terms calculated to delay or prevent a change in control of our Company or make removal of management more difficult. If our board of directors decides to issue preferred shares, the price of the ADSs may fall, and the voting and other rights of the holders of our ordinary shares and ADSs may be materially and adversely affected.

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 in the Cayman Islands. Our corporate affairs are governed by our second amended and restated memorandum and articles of association, the Companies Act (as amended) of the Cayman Islands, or the Companies Act, and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands (as compared to the United States) 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 (except for those decisions handed down from the Judicial Committee of the Privy Council to the extent that these have been appealed from the Cayman Islands courts). The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are broadly similar to those other common law jurisdictions, but there may be differences in the statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different 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, if shareholders want to proceed against us outside of the Cayman Islands, they will need to demonstrate that they have standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records or to obtain corporate records (other than the memorandum and articles of association, the register of mortgages and charges and any special resolutions passed by shareholders) or to obtain copies of lists of shareholders of these companies. Under Cayman Islands law, the names of our current directors can be obtained from a search conducted at the Registrar of Companies in the Cayman Islands. Our directors have discretion under our second amended and restated 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's motion or to solicit proxies from other shareholders in connection with a proxy contest.

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 management or members of the board of directors than they would as public shareholders of a company incorporated in the United States.

Certain judgments obtained against us by our shareholders may not be enforceable.

We are a Cayman Islands exempted company, and the majority of our assets are located outside of the United States. The majority of our current operations are conducted in China. Service of court documents on a Cayman Islands company can be effected by serving the documents at the Company's registered office and it may be possible to enforce foreign judgments in the Cayman Islands against a Cayman Islands company, subject to some exceptions.

However, if investors wish to serve documents on and/or enforce foreign judgments against our directors and officers, they will need to ensure that they comply with the rules of the jurisdiction where the directors and officers are located. In addition, the majority of our current directors are nationals and residents of countries other than the United States. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the United States in the event that you believe that your rights have been infringed under the U.S. federal securities laws or otherwise. Even if you are successful in bringing an action of this kind, there are significant legal and other obstacles to obtaining information needed for such actions and the laws in the Cayman Islands, PRC and Hong Kong may render you unable to enforce a judgment against our assets of our directors and officers, depending on where our directors and officers are located. For example, in China, 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. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no organization or individual may provide the documents and materials relating to securities business activities to overseas parties. See also “—Risks related to our ordinary shares and the ADSs—You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law” for risks associated with investing in us as a Cayman Islands company.

The voting rights of holders of ADSs are limited by the terms of the deposit agreement, and you may not be able to exercise your right to direct how the ordinary shares which are represented by the ADSs are voted.

Holders of ADSs do not have the same rights as our registered shareholders. As a Holder of our ADSs do not have any direct right to attend general meetings of our shareholders or to cast any votes at such meetings. Instead, holders are only able to exercise the voting rights which are carried by the underlying ordinary shares represented by the ADSs indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. Under the deposit agreement, holders may vote only by giving voting instructions to the depositary. If we instruct the depositary to ask for holders' instructions, then upon receipt of your voting instructions, the depositary will try, as far as is practicable, to vote the underlying ordinary shares which are represented by the ADSs in accordance with such instructions. If we do not instruct the depositary to ask for holders' instructions, the depositary may still vote in accordance with instructions given, but it is not required to do so. Holders of ADSs are not able to directly exercise their right to vote with respect to the underlying ordinary shares represented by the ADSs unless they cancel and withdraw such shares and become the registered holder of such shares prior to the record date for the general meeting.

Under our second amended and restated memorandum and articles of association, the minimum notice period required to be given by our Company to our registered shareholders to convene a general meeting, other than an annual general meeting, is at least 21 days. When a general meeting is convened, holders of ADSs may not receive sufficient advance notice of the meeting to withdraw the underlying ordinary shares represented by the ADSs and become the registered holder of such shares to allow attendance at the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. In addition, under our second amended and restated memorandum and articles of association, for the purposes of determining those shareholders who are entitled to attend and vote at any general meeting, our directors may close our register of members or fix in advance a record date for such meeting, and such closure of our register of members or the setting of such a record date may prevent holders of ADSs from withdrawing the underlying ordinary shares represented by the ADSs and becoming the registered holder of such shares prior to the record date, such that they would not be able to attend the general meeting or to vote directly. If we ask for holders' instructions, the depositary will notify the holders of the upcoming vote and will arrange to deliver our voting materials to the holders. We cannot assure holders that they will receive the voting materials in time to ensure that you can instruct the depositary to vote the underlying ordinary shares represented by the ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for their manner of carrying out holders' voting instructions. This means that the holders of ADSs may not be able to exercise their right to direct how the underlying ordinary shares represented by the ADSs are voted and may have no legal remedy if the underlying ordinary shares represented by the ADSs are not voted as requested.

The depositary for the ADSs will give us a discretionary proxy to vote our ordinary shares underlying the ADSs if holders of ADSs do not vote at shareholders' meetings, which could adversely affect holders' interests.

Under the deposit agreement for the ADSs, if holders of ADSs do not vote, the depositary may give us a discretionary proxy to vote the ordinary shares underlying the ADSs at shareholders' meetings if:

- we have timely provided the depositary with notice of meeting and related voting materials;
- we have instructed the depositary that we wish a discretionary proxy to be given;
- we have informed the depositary that there is no substantial opposition as to a matter to be voted on at the meeting; and
- a matter to be voted on at the meeting would not have a material adverse impact on shareholders.

The effect of this discretionary proxy is that if holders of ADSs do not vote at shareholders' meetings, they cannot prevent the ordinary shares underlying the ADSs from being voted, except under the circumstances described above. This may make it more difficult for shareholders to influence the management of our Company. Holders of our ordinary shares are not subject to this discretionary proxy.

We and the depositary are entitled to amend the deposit agreement and to change the rights of ADS holders under the terms of such agreement, and we may terminate the deposit agreement, without the prior consent of the ADS holders.

We and the depositary may amend or terminate the deposit agreement without the consent of the holders of ADSs. Such amendment or termination may be made in favor of our Company. Holders of the ADSs, subject to the terms of the deposit agreement, shall be given at least 30 days' notice of any amendment that imposes or increases any fees or charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, SWIFT, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADS holders. If you continue to hold the ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended. The depositary may, and shall at our written direction, terminate the deposit agreement and the ADSs by mailing notice of such termination to the registered holders of ADSs at least 30 days prior to the date fixed in such notice for such termination. After instructing its custodian to deliver all ordinary shares to us along with a general stock power that refers to the names set forth on the ADS register maintained by the depositary and providing us with a copy of the ADS register maintained by the depositary, the depositary and its agents will perform no further acts under the deposit agreement or the ADSs and shall cease to have any obligations under the deposit agreement and/or the ADSs.

Holders of ADSs may not receive dividends or other distributions on our ordinary shares, and you may not receive any value for them, if it is illegal or impractical to make them available to such holders.

The depositary of the ADSs may agree to distribute, subject to the terms of the deposit agreement, the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You would receive these distributions in proportion to the number of ordinary shares the ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act but that are not properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not feasible to distribute certain property. Additionally, the value of certain distributions may be less than the cost of distribution. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs and ordinary shares.

ADS holders may experience dilution of their holdings due to inability to participate in rights offerings.

We may, from time to time, distribute rights to our shareholders, including rights to acquire securities. Under the deposit agreement, the depositary will not distribute rights to holders of ADSs unless the distribution and sale of rights and the securities to which these rights relate are either exempt from registration under the Securities Act with respect to all holders of ADSs, or are registered under the provisions of the Securities Act. The depositary may, but is not required to, attempt to sell these undistributed rights to third parties, and may allow the rights to lapse. We may be unable to establish an exemption from registration under the Securities Act, and we are under no obligation to file a registration statement with respect to these rights or underlying securities or to endeavor to have a registration statement declared effective. Accordingly, holders of ADSs may be unable to participate in our rights offerings and may experience dilution of their holdings as a result.

ADS 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 plaintiffs in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our 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 U.S. Supreme Court. However, we believe that a pre-dispute contractual waiver of jury trial 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 non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a pre-dispute contractual waiver of jury trial, courts will generally consider whether a party knowingly, intelligently and voluntarily waived 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. The jury trial waiver provision may result in increased costs to ADS holders to bring a claim, limited access to information and other imbalances of resources between our Company and our ADS holders, and such provision could discourage claims or limit our ADS holders' ability to bring a claim in a judicial forum that they find favorable.

If you or any other holders or beneficial owners 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 and the depositary. If a lawsuit is brought against either or both of us and 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, including results that could be less favorable to the plaintiffs 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. 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.

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 are 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 of quarterly reports on Form 10-Q or current reports on Form 8-K with the SEC;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act; and
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD.

We will, however, 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 semi-annual basis through press releases, distributed pursuant to the rules and regulations of Nasdaq. Press releases relating to financial results and material events will also be furnished to the SEC on Form 6-K.

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 which would be made available to you were you investing in a U.S. domestic issuer.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short- swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain Nasdaq corporate governance requirements. As a U.S.-listed public company that is not a foreign private issuer, we would incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange.

We currently report our financial results under IFRS, which differs in certain significant respect from U.S. generally accepted accounting principles, or U.S. GAAP.

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS with those companies that prepare financial statements under U.S. GAAP.

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

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 compared to those that are otherwise applicable generally to public companies. These provisions include exemption from the auditor's attestation requirement under Section 404 of the Sarbanes-Oxley Act in the assessment of the emerging growth company's internal control over financial reporting. As a result, if we elect not to comply with such 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. Pursuant to the JOBS Act, we have elected to take advantage of the benefits of this extended transition period for complying with new or revised accounting standards as required when they are adopted for public 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 who have adopted the new or revised accounting standards.

We have experienced increased costs as a result of being a public company in the United States and expect such costs to increase after we cease to qualify as an “emerging growth company.”

We have incurred additional significant legal, accounting and other expenses after becoming a public company in the United States. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and Nasdaq, impose various requirements on the corporate governance practices of public companies. For example, as a result of becoming a public company, we had to increase the number of independent directors and adopt policies regarding internal controls and disclosure controls and procedures. It may also be more difficult for us to find qualified persons to serve on our board of directors or as executive officers. We cannot predict or estimate with any degree of certainty the amount of additional costs we may incur or the timing of such costs.

As an emerging growth company, we may take advantage of specified reduced reporting and other requirements compared to those that are otherwise applicable generally to public companies. These provisions include exemption from the auditor’s attestation requirement under Section 404 of the Sarbanes-Oxley Act in the assessment of the emerging growth company’s internal control over financial reporting. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year during which we have total annual gross revenues of at least US\$1.235 billion; (2) the last day of our fiscal year following the fifth anniversary of the completion of our U.S. initial public offering; (3) the date on which we have, during the preceding three-year period, issued more than US\$1.0 billion in non-convertible debt; or (4) the date on which we are deemed to be a “large accelerated filer” under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if we have been a public company for at least 12 months and the market value of the ADSs and ordinary shares that are held by non-affiliates exceeds US\$700 million as of the last business day of our most recently completed second fiscal quarter. 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 and the other rules and regulations of the SEC.

As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance standards; these practices may afford less protection to shareholders than they would enjoy if we comply fully with the Nasdaq corporate governance standards.

We are listed on Nasdaq and subject to the Nasdaq corporate governance rules. However, Nasdaq rules permit 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 standards. Our shareholders may be afforded less protection than they would otherwise enjoy under the Nasdaq corporate governance standards applicable to U.S. domestic issuers.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Ascentage Pharma Group Corp Limited, a company incorporated in Hong Kong with limited liability, or Ascentage Pharma (HK), was established in May 2009. Dr. Yang, Dr. Zhai, Dr. Wang and Dr. Guo, our co-founders, were the initial majority shareholders of Ascentage Pharma (HK).

In June 2010, Jiangsu Ascentage Pharma Co., Ltd, a limited liability company incorporated under the laws of the PRC, or Ascentage Jiangsu, was established as a wholly-owned subsidiary of Ascentage Pharma (HK).

Ascentage Pharma (HK) went through a series of internal restructurings and equity financings in 2015 and 2016, pursuant to which Ascentage International Limited, a limited liability company incorporated in Hong Kong, or Ascentage International, Hongkong Sansheng Medical Limited, a company incorporated in Hong Kong with limited liability, and Shengda Taizhou Investment Centre LLP, or Shengda Taizhou, acquired equity interests in Ascentage Jiangsu from Ascentage Pharma (HK). Shengda Taizhou held the equity interest in Ascentage Jiangsu for the benefit of Dr. Yang, Dr. Guo, Dr. Wang and Dr. Zhai.

In December 2016, Ascentage Jiangsu entered into a share transfer agreement for the acquisition of the entire equity interest of Guangzhou Healthquest Pharma Co., Ltd., or Healthquest Pharma from Dr. Zhai and Ren Jing. See “*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Healthquest acquisition.*”

In November 2017, we commenced a reorganization, or the Reorganization, consisting of the following principal steps:

1. In November 2017, Ascentage Pharma Group International was incorporated as an exempted company with limited liability under the laws of the Cayman Islands;
2. In November 2017, Ascentage Pharma Group International acquired all the equity interests in Ascentage Pharma (HK) from Dr. Yang, Dr. Wang, Dr. Guo and Collected Mind, a business company incorporated in the British Virgin Islands with limited liability and a wholly-owned subsidiary of 3SBio Inc. (a company listed on the Main Board of the Hong Kong Stock Exchange (stock code: 1530)) after which Ascentage Pharma (HK) became a wholly-owned subsidiary of Ascentage Pharma Group International; and
3. In July 2018, Ascentage Pharma Group International acquired all of the equity interests in Ascentage International, from each of Dr. Yang, Dr. Wang and Dr. Guo, in exchange for which Ascentage Pharma Group International issued ordinary shares to Ascentage Limited, a company that was incorporated in the British Virgin Islands with limited liability which was owned by Dr. Yang (for himself and as settlor of the Yang Family Trust) as to 45.53%, Dr. Guo (for himself and as settlor of the Guo Family Trust) as to 27.69% and Dr. Wang (for himself and as settlor of the Wang Family Trust) as to 26.78%, in an amount calculated with reference to the registered capital amount owned by Ascentage International in Ascentage Jiangsu immediately preceding the acquisition, until the dissolution of Ascentage Limited in December 2023.

Upon the completion of the Reorganization, Ascentage Pharma became the top holding company of our company and its subsidiaries. Our daily operations are conducted primarily through our operating subsidiaries in mainland China, Hong Kong, the United States and Australia. Ascentage Pharma Group Corp Limited, Ascentage International Limited, Ascentage Investment International and Ascentage Investment Limited are investment holding intermediaries.

In October 2019, Ascentage Pharma completed its Hong Kong initial public offering in which it offered and sold an aggregate of 14,008,000 ordinary shares. On October 28, 2019, the ordinary shares began trading on the HKEx under the stock code “6855.”

On February 3, 2021, we entered into a placing and subscription agreement with Ascentage Limited, as the Vendor, and J.P. Morgan Securities (Asia Pacific) Limited and China International Capital Corporation Hong Kong Securities Limited, as placing agents. An aggregate of 26,500,000 existing ordinary shares owned by the Vendor were placed by the placing agents to not less than six placees at a price of HK\$44.20 per share and we subsequently issued to the Vendor the same number of 26,500,000 new ordinary shares at the same price of HK\$44.20 per share. The closing price of our ordinary shares on the HKEx on February 3, 2021, the date on which the terms of the placing were fixed, was HK\$48.80. The net proceeds (after deducting all applicable costs and expenses, including commission and levies) raised were approximately HK\$1,153.64 million.

On July 23, 2021, Innovent Biologics, Inc. subscribed for 8,823,863 of our ordinary shares at a price of HK\$44.00 per share, for a total consideration of HK\$388.25 million. The net proceeds (after deducting all applicable costs and expenses, including commission and levies) raised from the subscription were approximately HK\$388.06 million. The closing price of our ordinary shares on the HKEx on July 14, 2021, the date on which the terms of the subscription were fixed, was HK\$52.95.

On January 18, 2023, we entered into the 2023 Placing and Subscription Agreement with the Vendor and J.P. Morgan Securities (Asia Pacific) Limited, China International Capital Corporation Hong Kong Securities Limited and Citigroup Global Markets Limited, or the placing agents. An aggregate of 22,500,000 existing ordinary shares owned by the Vendor were placed by the placing agents to not less than six placees at a price of HK\$24.45 per share and we subsequently issued to the Vendor the same number of 22,500,000 new ordinary shares of the Company at the same price of HK\$24.45 per share. The closing price of our ordinary shares on the HKEx on January 18, 2023, the date on which the terms of the top-up placing was fixed, was HK\$24.05. The net proceeds (after deducting all applicable costs and expenses, including commission and levies) raised were HK\$543.9 million.

On June 20, 2024, pursuant to a Securities Purchase Agreement with Takeda, we issued and sold to Takeda 24,307,322 of our ordinary shares at a price per share equal to HK\$24.09850 (equivalent to approximately US\$3.08549), for an aggregate purchase price of US\$75 million. In connection therewith, we entered into a Registration Rights Agreement with Takeda, granting the Takeda certain registration rights. A copy of the Registration Rights Agreement is filed as Exhibit 4.15 to this Annual Report on Form 20-F.

In January 2025, Ascentage Pharma completed its U.S. initial public offering in which it offered and sold an aggregate of 8,260,144 ADSs (representing 33,040,576 ordinary shares). On January 24, 2025, the ADSs began trading on the Nasdaq Global Market under the symbol “AAPG.”

On July 14, 2025, we entered into the 2025 Placing and Subscription Agreement with Dajun Yang Dynasty Trust, a family trust established by Dr. Yang, as vendor, and J.P. Morgan Securities (Asia Pacific) Limited and Citigroup Global Markets Limited, as placing agents. An aggregate of 22,000,000 existing ordinary shares owned by the vendor were placed by the placing agents to not less than six placees at a price of HK\$68.60 per share and we subsequently issued to the vendor the same number of 22,000,000 new ordinary shares of the Company at the same price of HK\$68.60 per share. The closing price of our ordinary shares on the HKEx on July 14, 2025, the date on which the terms of the top-up placing was fixed, was HK\$74.70. The net proceeds (after deducting all applicable costs and expenses, including commission and levies) raised were HK\$1,492.5 million (US\$190.1 million).

In March 2026, the Board approved the transfer of ownership of Ascentage Pharma Group Inc., Ascentage Pharma Pty Ltd., and Ascentage Pharma Europe Limited from Ascentage Pharma Group Corp Ltd. to Ascentage Pharma to streamline the organizational structure, which the Company expects will occur in 2nd quarter of this year.

Our corporate headquarters are located at 68 Xinqing Road Suzhou Industrial Park, Suzhou, Jiangsu, China, and our telephone number is +1 (301) 291-5658. Our agent for service of process in the United States is Ascentage Pharma Group Inc., located at 700 King Farm Boulevard, Suite 510, Rockville, MD 20850, and its telephone number is +1 (301) 291-5658. Our registered office is located at the office of Walkers Corporate Limited, with the registered address of 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands. Our corporate website is www.ascentage.com. The information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report on Form 20-F, and you should not consider information on our website to be part of this Annual Report on Form 20-F. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, such as the Company, at <http://www.sec.gov>.

B. Business Overview

Overview

We are a global, commercial stage, integrated biopharmaceutical company engaged in the discovery, development and commercialization of novel, differentiated therapies to address unmet medical needs in cancer. For more than two decades, our founders and team have leveraged their deep expertise to develop our proprietary drug discovery platform to pursue particularly challenging targets and significant unmet global medical needs. Our lead assets, Olverembatinib and Lisoftoclax, have global potential to address the major hematological malignancies, including chronic myeloid leukemia, or CML, acute myeloid leukemia, or AML, chronic lymphocytic leukemia, or CLL, acute lymphocytic leukemia, or ALL, myelodysplastic syndrome, or MDS, which is expected to exceed US\$166 billion in aggregate market size by 2035, according to the F&S Report.

Our first lead asset, Olverembatinib, is a novel, third-generation tyrosine kinase inhibitor, or TKI. Olverembatinib was the first BCR-ABL1 inhibitor approved in China for the treatment of patients with CML in chronic phase, or CML-CP, with T315I mutations, CML in accelerated phase, or CML-AP, with T315I mutations, and CML-CP that is resistant and/or intolerant to first and second-generation TKIs. We are currently commercializing Olverembatinib in China. All commercialized indications of Olverembatinib have been included in the National Drug Reimbursement List, or NRDL, in China beginning January 2025.

We believe that Olverembatinib, with its real-world patients' data in China, where it is approved, has the potential to be a global therapy for CML. The global CML market was around US\$12.3 billion in 2023 and is expected to grow to US\$14.6 billion by 2035, according to the F&S Report. We are currently conducting a registrational Phase 3 trial, or POLARIS-2, of Olverembatinib as a monotherapy for CML that is cleared by the U.S. Food and Drug Administration, or FDA, and European Medicines Agency or EMA. The clinical data obtained in China may not be accepted by the FDA or other foreign regulators to support ongoing or future clinical trials, and Olverembatinib is approved only in China, such that the outcome of our ongoing clinical trials is uncertain. We are also pursuing label expansion of Olverembatinib in combination with chemotherapy for the treatment of first-line Philadelphia chromosome-positive ALL, or frontline Ph+ ALL, in an FDA and EMA cleared registrational Phase 3 trial, or POLARIS-1, and conducting another registrational Phase 3 trial, or POLARIS-3 evaluating Olverembatinib as a monotherapy for succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor, or GIST.

Our second lead asset, Lisoftoclax, is a novel Bcl-2 inhibitor that we are developing for the treatment of various hematological malignancies. In November 2024, we announced that our NDA for the treatment of relapsed and/or refractory, or R/R, CLL and small lymphocytic lymphoma, or SLL, was accepted with Priority Review designation by the Center of Drug Evaluation, or CDE, of China's National Medical Products Administration, or NMPA. We believe this NDA is the second NDA filed in the world for a Bcl-2 inhibitor and the first in China for a Bcl-2 inhibitor for the treatment of patients with CLL/SLL that are resistant or intolerant to Bruton's tyrosine kinase, or BTK, inhibitors. Lisoftoclax was approved in China by the NMPA for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy including BTK inhibitors in July 2025. We started commercializing in China in July 2025 shortly after receiving approval. We intend to seek approval in multiple countries outside of China.

The global CLL/SLL market was around US\$9.4 billion in 2023 and is expected to grow to US\$38.2 billion by 2035, according to the F&S Report. We are also conducting an FDA-regulated registrational Phase 3 trial, or GLORA, of Lisoftoclax in combination with BTK inhibitors for patients with CLL/SLL previously treated with BTK inhibitors for more than 12 months with sub-optimal response and pursuing approval of Lisoftoclax for frontline CLL/SLL in a registrational Phase 3 trial, or GLORA-2, of Lisoftoclax in combination with acalabrutinib.

We believe that Lisoftoclax, with its short half-life and potential for patient-friendly ramp-up schedule, can serve as a backbone molecule for combination therapies for many hematological malignancies, including and beyond CLL/ SLL. Therefore, we are also evaluating Lisoftoclax in combination with azacitidine, or AZA, in two registrational Phase 3 trials, GLORA-3 (EMA and CDE cleared) and GLORA-4 (FDA, EMA and CDE cleared), for the frontline treatments of elderly, or unfit patients with AML or patients with higher risk, or HR, myelodysplastic syndrome, or MDS, respectively.

Backed by our strong scientific foundation, knowledge of small molecule discovery and capabilities to conduct clinical trials worldwide, we use state-of-the-art technologies to develop innovative therapeutic agents to treat cancers and address unmet medical needs within this patient population. Our initial focus has been to leverage our expertise in chemistry to synthesize inhibitors targeting proteins and pathways that drive the key hallmarks of cancer. Earlier in our pipeline, we are harnessing our understanding of protein degraders to develop therapies, such as proteolysis targeting chimera molecules, or PROTACs, that target traditionally undruggable proteins that are implicated in oncogenesis.

We are empowered by our technical expertise in structure-based drug design and our innovative drug discovery engine, which allows us to address unmet medical needs by targeting key apoptotic pathways and validated tyrosine kinases. These core competencies have allowed us to develop small molecule and degrader therapies targeted at Bcl-2, Bcl-2/Bcl-xL, IAP and MDM2, in addition to building next-generation cell signaling inhibitors (i.e., BCR- ABL1, ALK, FAK inhibitors) and epigenome-modifying agents (i.e., PRC2 inhibitor). We are the only Company in the world with active clinical programs targeting all three known classes of key apoptosis regulators, according to the F&S Report. We have nine ongoing U.S. and/or international registrational trials, including four that are FDA-cleared, for our two key clinical-stage assets. Beyond our two lead assets, we have several other clinical-stage assets in U.S. or international clinical trials.

Leveraging our robust internal research and development capabilities, we have built a portfolio of global intellectual property rights. We have also established collaborations and other relationships with leading biotechnology and pharmaceutical companies around the world, including a collaboration and license agreement with Innovent and clinical collaboration agreements with AstraZeneca, Merck, and Pfizer, and research and development relationships with leading research institutions, including but not limited to Dana-Farber Cancer Institute, Mayo Clinic, MD Anderson Cancer Center, National Cancer Institute and the University of Michigan. As of December 31, 2025, we had 512 issued patents globally, 374 of which were issued outside of China.

We have assembled a talented, global team with experience in the research and development of innovative drugs, as well as commercial manufacturing, sales and marketing. Our success is shaped by this global team of approximately 767 employees across the United States, Europe, Australia, and China, as of December 31, 2025. Together, we are dedicated to continuously strengthening our research and development capabilities and accelerating the clinical development progress of our product pipeline with the goal of addressing the unmet medical needs of patients globally.

Our pipeline

We have a pipeline of seven clinical-stage small-molecule drug candidates. The following table summarizes our pipeline and the development status of each candidate as of December 31, 2025:

Compound	Target	Indication	Dose Escalation/ Dose Expansion	Clinical POC	Registrational Trial	Marketed
Olverembatinib (HQP1351)	BCR-ABL	CML ^{1, 2} CML, Ph+ ALL, SDH-deficient GIST				
Lisaftoclax (APG-2575)	Bcl-2 Selective	CLL/SLL ³ CLL/SLL, AML, MDS, MM				
APG-2449	FAK/ALK/ ROS1	NSCLC Ovarian cancer				
Alrizomadlin (APG-115)	MDM2-p53	ACC, MPNST, AML/MDS, pediatric solid tumors				
Pelcitoclax (APG-1252)	Bcl-2/Bcl-xL	NSCLC, SCLC, neuroendocrine tumors, NHL				
APG-5918	PRC2 Inhibitor	anemia, oncology				
APG-3288	BTK Degradar	B-cell lymphoma				

Note:

1. Approved in November 2021 in China for the treatment of adult patients with TKI-resistant CML-CP and CML-AP harboring the T315I mutation, has been included into the China 2022 NRDL effective March 1, 2023.
2. Approved in November 2023 in China for the treatment of adult patients with CML-CP resistant and / or intolerant first and second generation TKIs, has been included into the China 2024 NRDL effective January 1, 2025
3. In July 2025, Lisaftoclax was approved by NMPA in China for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy, including BTK inhibitors.

Our two lead FDA-cleared Phase 3 trials collectively address all five major hematological malignancies:

Summary of key completed and ongoing clinical trials for Olverembatinib

Clinical Program	Indication	Dose Escalation/ Dose Expansion	Clinical POC	Registrational Trial	Marketed
Pivotal Ph-II	CML-CP with/without T315I Mutation; CML-AP with T315I Mutation ^{1, 2}	Single-agent	Full approval and full coverage by NRDL		Marketed in China since 2021
POLARIS-2	CML	Single-agent	FDA, EMA, CDE, and PMDA cleared	Global Phase III Registrational Trial	
POLARIS-1	First-line Ph+ ALL	+ Chemo	FDA, EMA, and CDE(w/ BTD) cleared	Global Phase III Registrational Trial	
POLARIS-3	SDH-deficient GIST	Single-agent	CDE cleared	Multinational Phase III Registrational Trial	

Note:

1. Approved in November 2021 in China for the treatment of adult patients with TKI-resistant CML-CP and CML-AP harboring the T315I mutation, has been included into the China 2022 NRDL effective March 1, 2023.
2. Approved in November 2023 in China for the treatment of adult patients with CML-CP resistant and or intolerant first and second generation TKIs, has been included into the China 2024 NRDL effective January 1, 2025.

Summary of key completed and ongoing clinical trials for Lisaftoclax

Clinical Program	Indication	Dose Escalation/ Dose Expansion	Clinical POC	Registrational Trial	Marketed
Pivotal Ph-II	CLL/SLL ¹	Single-agent		Approved in China 2025	
GLORA	CLL/SLL sub-optimal BTKi response (Add-on)	+ BTK Inhibitor	FDA, EMA, and CDE cleared	Global Phase III Registrational Trial	
GLORA-2	First-Line CLL/SLL	+ acalabrutinib	EMA and CDE cleared	Multinational Phase III Registrational Trial	
GLORA-3	First-Line Elderly and Unfit AML	+ AZA (azacitidine)	EMA and CDE cleared	Multinational Phase III Registrational Trial	
GLORA-4	First-Line HR-MDS	+ azacitidine	FDA, EMA, and CDE cleared	Global Phase III Registrational Trial	

Note:

- 1 In July 2025, Lisaftoclax was approved by NMPA in China for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy including BTK inhibitors.

Olverembatinib (HQP1351), our first lead asset, is a novel, third-generation TKI. Olverembatinib is the first BCR-ABL1 inhibitor approved in China for patients with CML-CP with *T315I* mutations, CMP-AP with *T315I* mutations and CML-CP that is resistant and/or intolerant to first and second-generation TKIs. Since January 2025, all approved indications of Olverembatinib are covered by the China NRDL, which bolstered the affordability and accessibility of the drug in China.

Olverembatinib was included as an Emerging Treatment Option in the 2024 National Comprehensive Cancer Network (NCCN) USA guidelines for the management of CML and in the updated 2025 European LeukemiaNet recommendations. In addition, Olverembatinib has been included in the 2025 edition of the Chinese Medical Association’s Guidelines for the Diagnosis and Treatment of Chronic Myeloid Leukemia in China, the 2025 edition of the Chinese Anti-Cancer Association (CACA) Guidelines for Holistic Integrative Management of Cancer, and the 2025 edition of the Chinese Society of Clinical Oncology (CSCO) Guidelines.

To date, the FDA has granted four orphan drug designations, or ODD, to Olverembatinib, including for the treatment of CML, ALL, AML and GIST, and fast track designation, or FTD, for the treatment of CML in patients with certain genetic markers who have failed to respond to treatments with existing TKIs. Olverembatinib was also granted an Orphan Designation by the European Medicines Agency, or EMA, for the treatment of CML. Through three registrational Phase 3 trials, we are currently evaluating Olverembatinib as a monotherapy and/or in combination with existing treatments for patients with CML, first-line patients with frontline Ph+ ALL, and patients with SDH-deficient GIST. Clinical trials evaluating Olverembatinib are currently taking place in Australia, various European countries, India, Canada, China and the United States. On February 25, 2025, the CDE of China NMPA granted Olverembatinib the breakthrough therapy designation for patients with first-line Ph+ ALL.

Lisafitoclax (APG-2575), our second lead asset, is a novel Bcl-2 inhibitor that we are developing for the treatment of various hematological malignancies. To date, the FDA has granted five ODDs to Lisafitoclax, including for the treatment of CLL, AML and MM. In November 2024, we announced that our NDA was accepted with Priority Review designation by the CDE. On July 10, 2025, Lisafitoclax was approved by China's NMPA for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy including BTK inhibitors, which makes Lisafitoclax the first Bcl-2 inhibitor receiving conditional approval and marketing authorization for the treatment of patients with CLL/SLL in China, and the second Bcl-2 inhibitor approved globally. Shortly after the approval, we have commenced the commercial sales of Lisafitoclax in China. According to the F&S Report, this NDA is the second NDA filed in the world for a Bcl-2 inhibitor and the first in China for a Bcl-2 inhibitor for the treatment of patients with CLL/SLL that are resistant or intolerant to BTK inhibitors. Through four registrational Phase 3 trials, we are currently evaluating Lisafitoclax as a monotherapy and/or in combination with existing treatments for patients with CLL/SLL, AML and MDS. We are also evaluating Lisafitoclax in ongoing clinical trials for MM and other hematological malignancies. Clinical trials evaluating Lisafitoclax are currently taking place in Australia, Belgium, Canada, China, France, Germany, Hungary, Japan, Poland, Spain, United Kingdom and the United States.

Alrizomadlin (APG-115) is a novel, orally bioavailable, highly selective, small molecule inhibitor of the mouse double minute 2, or MDM2, homolog, or MDM2-p53. We believe Alrizomadlin has potential to treat a number of serious rare and orphan diseases and address unmet medical needs in both adult and pediatric indications.

The FDA has granted six ODDs for Alrizomadlin for the treatment of soft-tissue sarcoma, gastric cancer, AML, retinoblastoma, stage IIB-IV melanoma, and neuroblastoma. In addition, Alrizomadlin has been granted two Rare Pediatric Disease Designations, or RPDD designations by the FDA for the treatment of neuroblastoma and retinoblastoma.

To date, the FDA has granted six ODDs and two rare pediatric disease designations, or RPDD, for Alrizomadlin. Clinical trials evaluating Alrizomadlin are currently taking place in Australia, China and the United States. A Phase I clinical study of Alrizomadlin alone or in combination with Lisafitoclax in children with solid tumors is ongoing; current data indicates that Alrizomadlin alone or in combination with Lisafitoclax showed a manageable safety profile, with preliminary antitumor activity in heavily pretreated relapsed/metastatic rhabdomyosarcoma (RMS) or other soft-tissue sarcomas (STSs).

Pelcitoclax (APG-1252) is a novel, highly potent, small molecule drug designed to restore apoptosis through dual inhibition of the Bcl-2 and Bcl-xL proteins. To date, the FDA has granted one ODD to Pelcitoclax for the treatment of small cell lung cancer, or SCLC. We are currently evaluating Pelcitoclax in two Phase 1b trials and one Phase 1b/2 trial for the treatment of patients with non-small cell lung cancer, or NSCLC, neuroendocrine tumors or non-Hodgkin's lymphoma, or NHL. In October 2023, we presented preliminary results from the Phase 1b trial of Pelcitoclax in combination with osimertinib in patients with epidermal growth factor receptor-mutant, or EGFR- mutant, NSCLC at the 2023 Congress for the European Society for Medical Oncology, or ESMO, demonstrating potential therapeutic utility. Clinical trials evaluating Pelcitoclax are currently taking place in Australia, China and the United States.

APG-5918 is a potent, orally bioavailable, and highly selective inhibitor of the embryonic ectoderm development, or EED, a sub-unit of the Polycomb Repressive Complex 2, or PRC2. APG-5918 is a PRC2 inhibitor with demonstrated potential for treating patients with anemia, including beta-thalassemia and chronic kidney disease, or CKD-induced anemia and oncology, including TCLs, Prostate cancer and MM. During 2026, we will advance the clinical development of APG-5918 in oncology and anemia in the U.S. and China.

APG-2449 is a novel, orally active, small-molecule focal adhesion kinase (FAK), the third generation of anaplastic lymphoma kinase (ALK) and receptor tyrosine kinase C-ros oncogene 1 (ROS1) triple ligase kinase inhibitor (TKI) designed and developed by Ascentage Pharma. It is the first FAK inhibitor approved by CDE for clinical study in China. In the first-in-human trial, cerebrospinal fluid PK analyses showed that APG-2449 was brain-penetrant. An updated study of APG-2449 demonstrated preliminary clinical benefit in patients with NSCLC whose disease was TKI naïve and resistant to 2G ALK inhibitors, especially in brain metastases. In addition, high pFAK expression levels in baseline tumor tissue correlated with improved APG-2449 treatment responses in patients with NSCLC resistant to 2G ALK inhibitors, suggesting that the increase of pFAK may be associated with second-generation ALK TKI resistance. In October 2024, APG-2449 was cleared by the Center for Drug Evaluation (CDE) of China's National Medical Product Administration (NMPA) to enter two registrational Phase III studies that will separately evaluate APG-2449 in patients with non-small cell lung cancer (NSCLC) who are resistant to or intolerant of second-generation anaplastic lymphoma kinase (ALK) TKIs; and treatment-naïve patients with ALK-positive advanced or locally advanced NSCLC.

APG-3288 is the first novel, highly potent and selective BTK degrader developed utilizing Ascentage Pharma's proprietary proteolysis-targeting chimera (PROTAC) technology platform. This candidate induces the formation of a ternary complex consisting of the BTK target, the PROTAC, and the Cereblon E3 ubiquitin ligase, leading to proteasome-mediated degradation of the BTK target. Unlike conventional BTK inhibitors, APG-3288 is designed to act through degradation rather than inhibition, inducing rapid, potent, highly selective, and sustained degradation of both wild-type BTK and multiple BTK mutants associated with resistance to existing BTK inhibitors. Critically, this approach blocks the BCR-BTK signaling axis at its source, thereby overcoming resistance to BTK inhibitors and potentially providing a novel and differentiated therapeutic strategy for BTK-targeted treatment. In preclinical studies, compared to other BTK degraders in development, APG-3288 demonstrated more potent BTK degradation, higher selectivity, and more favorable PK properties that highlighted the drug's potential.

Our competitive strengths

We believe our Company is differentiated by several strengths, including:

- Global, integrated biopharmaceutical company with discovery, development, manufacturing and commercialization capabilities, strategically targeting the global hematological malignancies market, estimated to be US\$67.2 billion in 2023 and rising to US\$208.8 billion by 2035 according to the F&S Report;
- Strong and well-established in-house discovery team;
- Integrated clinical development team working across China, US, UK and Australia;
- Our 200,000 square foot manufacturing facility provides clinical and commercial supply of drug products, including support of all of our clinical trials;
- Full commercial team comprised of more than 270 members in China together with U.S.-based senior leadership with significant global commercialization and sales experience;
- Our two lead FDA-cleared Phase 3 assets that are collectively addressing all five major hematological malignancies;
- Strong market position with Olverembatinib, a novel third-generation BCR-ABL1 TKI, commercialized in China since 2021 with real- world patient data, validating global development and commercialization plans and Lisoftoclax, a novel Bcl-2 inhibitor, commercialized in China since July 2025 for the treatment of various hematological malignancies globally, including and beyond CLL/SLL;
- Deep expertise and insights in developing small molecule drugs for challenging targets and high unmet medical needs;
- Our innovative pipelines with global potential and ongoing clinical trials in Australia, Canada, China, various European countries, Japan, United Kingdom, India and the United States that are driven by the proprietary drug discovery platform and technologies such as chemical synthesis and targeted protein degradation; and
- Dedicated science-driven international team with complementary knowledge and skillsets, led by visionary founders working together for more than 20 years.

Disease and industry background

All the information and data, including statistics and estimates, for the diseases described in this section and elsewhere in this Annual Report on Form 20-F including the markets and forecasts regarding the diseases have been derived from the F&S Report.

Hematologic malignancies, or blood cancers, affect the production and function of blood cells. These cancers typically begin in the bone marrow where blood is produced. Blood cancers, like all cancers, are characterized by the overproduction of an abnormal type of cell. Blood cancer cells do not form solid tumors, but their uncontrolled growth crowds out normal cells in the blood, bone marrow or plasma, preventing normal cells from developing and performing important functions.

Each hematologic malignancy has various subtypes as well. Blood cancers are estimated to account for about 10% of all new cancer diagnoses globally. Approximately 1.5 million new cases of blood cancer cases were diagnosed globally, and the global incidence is expected to reach 1.8 million by 2035. Approximately 720,000 people die from blood cancer every year, accounting for more than 7% of cancer deaths. The global market for hematological malignancies was US\$67.2 billion in 2023, representing approximately 30% of the cancer therapy market, and expected to grow to approximately US\$208.8 billion by 2035.

Survival rates for most hematologic malignancies have improved over time, likely due to the introduction of new and more effective treatments, include chemotherapy, radiation, targeted therapy, stem cell transplant, immunotherapy and cell or gene therapy.

Leukemia is a group of blood cancers characterized by abnormal, uncontrolled white blood cell growth that usually begins in the bone marrow, where most of the body's blood is produced. In some cases, such as acute leukemias, these blood cells are not fully developed. In other cases, such as chronic leukemias, the mature cells are transformed and become leukemic. Clinically and pathologically, leukemia is subdivided into a variety of large groups. According to the blood cells affected and disease progression, leukemia is mostly composed of the following four types: chronic myeloid leukemia, or CML, acute myeloid leukemia, or AML, chronic lymphocytic leukemia, or CLL, and acute lymphocytic leukemia, or ALL.

Chronic myeloid leukemia (CML)

Chronic myeloid leukemia, or CML, also known as chronic myelogenous leukemia, chronic granulocytic leukemia and chronic myelocytic leukemia, is a rare cancer that is characterized by the increased and unregulated growth of myeloid cells in the bone marrow and the accumulation of these cells in blood and other organs. CML is divided into three phases: chronic phase, or CML-CP, accelerated phase, or CML-AP, and blast crisis phase, or CML-BP. Most patients with CML are diagnosed at the chronic phase. In the chronic phase, less than 10 percent of blood and bone marrow cells are immature white blood cells, also known as blasts. In the accelerated phase, the number of blast cells in the blood and bone marrow exceeds normal levels.

In Western countries, CML accounts for 15 to 25% of all adult leukemias and 14% of leukemias overall, including the pediatric population where CML is less common. In 2023, the global incidence of CML was approximately 51.6 thousand with a compound annual growth rate, or CAGR, of 3.2%, and it is projected that the incidence of CML will continue to grow up to 64.6 thousand in 2035. The global CML market was around US\$12.3 billion in 2023 and is expected to grow to US\$14.6 billion by 2035.

Acute lymphocytic leukemia (ALL)

Acute lymphocytic leukemia, or ALL, is a rare cancer characterized by a rapid increase and large numbers of immature or dedifferentiated blood cells, called lymphoblastic cells. These blood cells never grow up to function as normal cells due to DNA damage.

The incidence rate of ALL is closely related to age and gender. Around 60% of ALL cases are diagnosed before the age of 20, and compared to females, males are more likely to develop ALL. ALL primarily affects children and is the most common type of childhood cancer. According to the American Cancer Society, or ACS, it is estimated that in 2024 there will be approximately 6,550 new cases of ALL (3,590 in males and 2,960 in females) and approximately 1,330 deaths from ALL (640 in males and 690 in females) in the United States. In pediatric patients, which account for approximately 50% of ALL cases, the chance of cure is approximately 80%. ALL can also occur in adults, though the prognosis is generally worse in older patients with approximately a 45 to 60% chance of cure and poorer prognosis in patients who are 60 years or older. According to ACS, about 80% deaths from ALL in the United States occur in adults. According to the F&S Report, the five-year overall survival rate is 40.0% in adults in the United States and is 17.6% in adults in China.

There were around 120.3 thousand new cases of ALL in 2023 with expected growth to 150.5 thousand in 2035. Since the molecular basis of ALL is complex, comprising various genetic and environmental factors, the incidence of ALL will remain relatively stable in the future. The global drug market of ALL was around US\$3.7 billion in 2023 and is expected to grow up to US\$26.9 billion by 2035.

Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia, or Ph+ ALL, is the most common cytogenetic abnormality in adult patients with ALL, occurring in about 20% to 30% of all cases. It results from a reciprocal translocation between the ABL1 oncogene on the long arm of chromosome 9 and a breakpoint cluster region, or BCR, on the long arm of chromosome 22, resulting in a fusion gene, BCR-ABL1, that encodes an oncogenic protein with constitutively active tyrosine kinase activity. The incidence of Ph+ ALL increases with age, from less than 5% in younger children to 20% to 25% in older adults. There were around 18.3 thousand new cases of Ph+ ALL patients in 2023 with expected growth to 23.1 thousand in 2035.

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)

Chronic lymphocytic leukemia, or CLL and small lymphocytic lymphoma, or SLL, are two slow-growing hematological malignancies commonly grouped together as a type of non-Hodgkin lymphoma. In CLL, the cancer cells start in the bone marrow and slowly progresses to the blood, whereas in SLL, the cancer cells are primarily found in the lymph nodes and spleen, but both CLL and SLL behave similarly and are treated in the same way.

Although the exact causes of CLL and SLL are unknown, it primarily affects older populations and is among the most common leukemia subtypes in adults, accounting for a quarter of all leukemia cases in Western countries.

Advancements in basic research and targeted therapies have brought significant survival benefits to patients with CLL/SLL. Despite advancements in new targeted therapies, CLL/SLL still presents major clinical challenges and remains an urgent medical need for new treatment options that can offer both efficacy and safety.

According to ACS, it is estimated that in 2024 there will be approximately 20,700 first-line cases and 4,440 deaths from CLL in the United States. In China, CLL/SLL is occurring at a rapidly rising incidence rate, with a younger age of onset and higher aggressiveness, thus posing a serious threat to public health in the country with global incidence expected to increase to 119.5 thousand in 2035. The global CLL/SLL market was around US\$9.4 billion in 2023 and is expected to grow to US\$38.2 billion by 2035.

Acute myeloid leukemia (AML)

AML is a rapidly progressing hematological malignancy that typically affects older patients. According to ACS, it is estimated that in 2024 there will be approximately 20,800 first-line cases and 11,220 deaths from AML in the United States. The average age of diagnosis is currently at approximately 68 years of age, but it can also occur in children. Variables that are used to predict a patient's prognosis and influence treatment strategies include age, antecedent MDS, and cytogenetic abnormalities. Increasingly, there are also a number of identified mutations (such as CEBPA, c-KIT, FLT3, IDH1/2, KMT2A-r/MLL-r, and NPM1) that can impact prognosis. According to the F&S Report, the five-year overall survival rate is 26.0% in adults in the United States and is less than 20.0% in adults in China. The global incidence of AML is estimated to be 97.6 thousand as of 2023 and is expected to reach 122.1 thousand by the end of 2035.

It is estimated that, globally, there were 97.6 thousand new cases of AML in 2023, which is projected to increase to 122.1 thousand in 2035. The global AML market was US\$3.9 billion in 2023 and is expected to grow to US\$10.8 billion by the end of 2035.

Myelodysplastic syndrome (MDS)

Myelodysplastic syndrome, or MDS, constitutes a broad spectrum of hematological malignancies. MDS results from clonal alterations in the bone marrow stem cells that can manifest as a variety of hematological abnormalities of varying severity. In some cases, the underlying cause of MDS is unknown, or primary MDS. More commonly, the condition develops following exposure to high doses of radiation, chemotherapy, or other toxins that damage the bone marrow stem cells. In about 1 in 3 patients, MDS can progress to AML. The incidence of MDS ranged from 0.22 to 13.2 per 100,000 population across different regions, age groups, genders, and ethnicities, and the incidence rate of it tend to be higher in more developed regions, such as North America, Europe, and Australia.

In 2023, there were around 94.9 thousand new cases of MDS worldwide. According to the F&S Report, the five- year overall survival rate is 31.3% in the United States and 27.0% in China. In Europe, there are an estimated 15,000 to 25,000 new cases diagnosed each year.

The global incidence of MDS is estimated to be 94.9 thousand as of 2023 and is expected to reach 104.1 thousand by the end of 2035.

Multiple Myeloma (MM)

Multiple myeloma, or MM, is a hematologic malignancy that results from an overproduction of plasma cells in the bone marrow. Normally, some B lineage cells mature into plasma cells whose sole function is to produce immunoglobulins, or Ig. In the case of MM, patients typically produce excessive amounts of a defective type of Ig called M protein that serves little function in protecting the host. However, these IgM-producing myeloma cells proliferate quickly and can crowd normal cells out of the marrow. As a result, hematopoietic deficiencies can develop, leading to anemia, leukopenia, thrombocytopenia, and a dependence on blood or platelet transfusions.

It is estimated that there are approximately 191.8 thousand new cases of MM globally in 2023, and the number of new cases is projected to increase to 257.9 thousand in 2035. According to the F&S Report, the five-year overall survival rate is 55% in adults in the United States and is 33.7% in adults in China.

The global drug market of MM was around US\$25.4 billion in 2023 and is expected to grow up to US\$75.8 billion by 2035.

Our products

Our first lead asset: Olverembatinib

Our first lead asset, Olverembatinib, is a novel, third-generation TKI. Olverembatinib is the first BCR- ABL1 inhibitor approved in China for the treatment of patients with CML-CP with *T315I* mutations, CML-AP with *T315I* mutations and CML-CP that is resistant or intolerant to first and/or second-generation TKIs. We believe that Olverembatinib, with its real-world patient data in China, where it is approved, has the potential to be a global drug for CML and Ph+ ALL.

In January 2023, Olverembatinib was included in China’s 2022 NRDL for the indications of *T315I*-mutant CML-CP and *T315I*-mutant CML-AP. Olverembatinib was included as an Emerging Treatment Option in the 2024 National Comprehensive Cancer Network (NCCN) USA guidelines for the management of CML and in the updated 2025 European LeukemiaNet recommendations. In addition, Olverembatinib has been included in the 2025 edition of the Chinese Medical Association’s Guidelines for the Diagnosis and Treatment of Chronic Myeloid Leukemia in China, the 2025 edition of the Chinese Anti-Cancer Association (CACA) Guidelines for Holistic Integrative Management of Cancer, and the 2025 edition of the Chinese Society of Clinical Oncology (CSCO) Guidelines.

In July 2024, Olverembatinib was approved by the Pharmaceutical Administration Bureau (ISAF) of the Macau Special Administrative Region of the People’s Republic of China for the treatment of adult patients with TKI-resistant CML-CP or CML-AP harboring the T315I mutation and adult patients with CML-CP resistant to and/or intolerant of first- and second-generation TKIs. Starting in 2025, all approved indications are covered by the NRDL in China, which further bolster the affordability and accessibility of the drug in China.

To date, the FDA has granted four ODDs to Olverembatinib, including for CML, ALL, AML and GIST, and FTD for the treatment of CML in patients with certain genetic markers who have failed to respond to prior TKIs. Olverembatinib was also granted an Orphan Designation by the European Medicines Agency, or EMA, for the treatment of CML. Previously, Olverembatinib was accepted by the CDE breakthrough therapy designation, or BTd, for the treatment of patients with SDH-deficient GIST who had received prior frontline treatment as well as first-line Ph+ ALL patients.

We are currently conducting an FDA and EMA cleared registrational Phase 3 trial, POLARIS-2, of Olverembatinib as a monotherapy for CML, and subject to the trial’s successful completion. We plan to pursue approvals in the US and other key countries. In parallel, we are pursuing label expansion of Olverembatinib in an FDA and EMA cleared registrational Phase 3 trial, or POLARIS-1, in combination with chemotherapy for the treatment of frontline Ph+ ALL and a registrational Phase 3 trial, or POLARIS-3, as a monotherapy for SDH-deficient GIST. We are continuing to enroll and expect to complete the majority of patient enrollment in POLARIS-1 in 2026.

Summary of key completed and ongoing clinical trials for Olverembatinib

Clinical Program	Indication	Dose Escalation/ Dose Expansion	Clinical POC	Registrational Trial	Marketed
Pivotal Ph-II	CML-CP with/without <i>T315I</i> Mutation; CML-AP with <i>T315I</i> Mutation ^{1, 2}	Single-agent	Full approval and full coverage by NRDL		Marketed in China since 2021
POLARIS-2	CML	Single-agent	FDA, EMA, CDE, and PMDA cleared	Global Phase III Registrational Trial	
POLARIS-1	First-line Ph+ ALL	+ Chemo	FDA, EMA, and CDE(w/ BTd) cleared	Global Phase III Registrational Trial	
POLARIS-3	SDH-deficient GIST	Single-agent	CDE cleared	Multinational Phase III Registrational Trial	

Note:

1. Approved in November 2021 in China for the treatment of adult patients with TKI-resistant CML-CP and CML-AP harboring the T315I mutation, has been included into the China 2022 NRDL effective March 1, 2023
2. Approved in November 2023 in China for the treatment of adult patients with CML-CP resistant and or intolerant first and second generation TKIs, has been included into the China 2024 NRDL effective January 1, 2025.

Current treatment paradigm and its limitations

Historically, the standard of care for CML and ALL was chemotherapy, which involves the use of cytotoxic drugs to kill cancer cells. However, chemotherapy alone was not curative and had limited effectiveness in controlling the disease. The introduction of TKIs revolutionized the treatment of CML and ALL. BCR-ABL1 is a leukemia-causing fusion gene that produces a dysfunctional protein called “BCR-ABL1 tyrosine kinase” that is biologically active, leading to the abnormal regulation of cell growth and survival and is associated with CML and certain types of ALL. TKIs are targeted therapies that are designed to specifically inhibit the BCR-ABL1 tyrosine kinase. Imatinib, or GLEEVEC, the first TKI approved by the FDA for CML, was highly effective initially but many CML and ALL patients developed resistance or intolerance. To address this, a number of second-generation TKIs were developed, but many patients also developed resistance or intolerance. Notably, first and second-generation TKIs have not been able to address patients with CML with *T315I* mutations, which was associated with rapid progression and limited survival. Although second-generation TKIs are widely used with an estimated US\$5.5 billion in annual sales in 2023 according to the F&S Report, there remains significant unmet medical need for CML.

More recently, third-generation TKIs have been developed to further enhance treatment outcomes. Ponatinib, or ICLUSIG, was approved by the FDA in December 2012 for the treatment of CML and Ph+ ALL in patients who are resistant or intolerant to prior generations of TKIs, or in cases where *T315I* mutations are present. However, ponatinib has been reported to cause severe thrombosis and is currently carrying a Black Box warning required by the FDA due to the excessive rate of vascular events (>27%), occurrence of heart failure (8%) and serious liver toxicity. For serious non-hematologic adverse events related to ponatinib, the FDA label recommends modifying the dose or stopping treatment. Dose modifications include decreasing dose by 15 milligrams (mg) from the recommended starting dose of 45 mg for each occurrence of an adverse event. A ponatinib dose-ranging study in CML-CP patients showed a dose-dependent reduction in response and concluded that the benefit/risk of dose reduction should be carefully assessed, especially among patients with *T315I* mutations. Despite these safety and efficacy trade-offs, ponatinib remains one of the only two approved drugs in the United States for patients with CML with *T315I* mutations and costs more than US\$200,000 per person per year. However, the U.S. patent for ponatinib is expected to expire in December 2026 and EU patent is expected to expire in June 2028.

Asciminib is an ABL1 allosteric inhibitor that was approved by the FDA in October 2021 for the treatment of CML-CP (following treatment with 2 prior TKIs) and for the treatment of CML-CP with *T315I* mutations. It was granted accelerated approval by the US Food and Drug Administration (FDA) for adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) in October 2024. Asciminib is mechanistically different than other TKIs in that it binds to the myristoyl pocket of the BCR-ABL1 protein instead of binding to the ATP-binding site of the kinase domain of the protein similar to other TKIs. However, patients with *T315I* mutations must receive 200 mg of asciminib twice daily, which is five times the regular dosage of asciminib for patients with CML without *T315I* mutations, and costs close to US\$1 million per person per year. Asciminib also has challenges with some specific compound mutations.

Despite the availability of ponatinib and asciminib, CML, whether with or without the *T315I* mutations or multiple and/or compound mutations, remains stubbornly resistant to approved therapies. Therefore, there remains a significant global unmet medical need and demand for more safe and effective therapies for patients with CML.

Our solution: Olverembatinib

Our first lead asset, Olverembatinib, is a novel third-generation TKI targeting multiple tyrosine kinases, including BCR-ABL1 mutants and multiple and/or compound mutations.

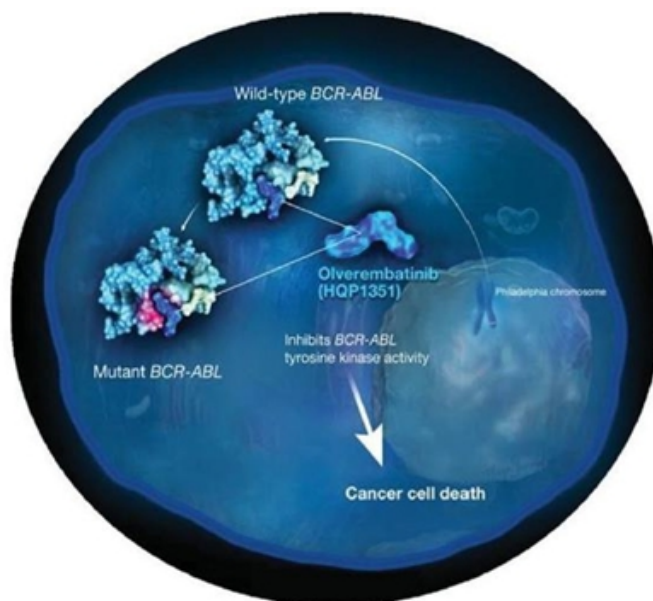
Mechanism of action

BCR-ABL1 is a fusion gene that occurs when pieces of chromosomes 9 and 22 break off and trade places, during cell division. Part of the ABL1 gene on chromosome 9 fuses to part of the BCR gene on chromosome 22. The new shorter chromosome 22 is called a “Philadelphia chromosome.” This abnormal gene produces the BCR-ABL1 protein, which is constantly active, acts upon a number of intracellular signal transduction pathways, and causes greater cell division and inhibiting apoptosis, which is programmed cell death. Cells with BCR-ABL1 tend to grow abnormally and divide out of control rather than undergo cell death. As a result, BCR-ABL1 is associated with CML, Ph+ ALL and some cases of AML.

Inhibition of BCR-ABL1 can block the abnormal cellular proliferation associated with disease and can subsequently trigger cell death. However, some BCR-ABL1 mutants, such as the *T315I* mutant type, have or can confer mutations that disrupt the binding of first and second generation TKIs, leading to resistance and allowing cancerous cells to survive and further proliferate.

Olverembatinib has a particularly high binding affinity for BCR-ABL1 and has been demonstrated to inhibit both the wild-type and the *T315I* mutant type of BCR-ABL1 triggering apoptosis of cancerous cells. Olverembatinib has also been shown to have a strong binding affinity to a number of other kinase targets, such as KIT, which has been implicated in SDH-deficient GIST.

Mechanism of Action of Olverembatinib



Our *in vitro* anti-proliferation assays of common BCR-ABL inhibitors and Olverembatinib demonstrated that Olverembatinib has strong inhibition of TKI kinase activity for the majority of BCR-ABL mutations, including *T315I* mutations, as well as multiple compound mutations.

Key clinical results

Olverembatinib has demonstrated a series of clinical data to date, as summarized below.

- Strong antileukemic activity in patients with heavily pretreated CML-CP, including *T315I* mutations, and Ponatinib and/or Asciminib failures, see “1. Strong antileukemic activity in Heavily Pretreated CML-CP Patients”
- Olverembatinib in combination with low-intensity chemotherapy showed efficacy in first-line Ph+ ALL Efficacy, see “2. POLARIS-1 Global Phase III Part 1 Results Olverembatinib + Low-intensity Chemotherapy in first-line Ph+ ALL”
- 72% CCyR and 44% MMR in adult CML-CP patients resistant and/or intolerant to 1L TKIs, see “3. Clinical benefit as a viable 2L Treatment for CML-CP”
- 76.5% patients achieved CR/CRh/CHR in in MLN-FGFR1 Mutant Patients, see “4. Olverembatinib Efficacy in MLN-FGFR1 Mutant Patients”
- Deep Remission and Improvement in allo-HSCT outcomes in BC-CML patients, see “5. Deep Remission, Improvement in Allo-HSCT Outcomes in Blast Crisis”
- Significantly longer EFS and better tolerability than BAT arm in CML-CP patients in a 4-year follow-up study, see “6. Registrational Phase II Study in CML-CP: 4-Year Follow Up”
- Olverembatinib in combination with venetoclax enhances allo-HSCT outcome, see “7. Olverembatinib + Bcl-2i Bridging: Potential for Chemo- or Immunotherapy Free Regimen with Lisafoclax”

All of the results presented above and below (other than “3. Clinical benefit in patients with ponatinib- and asciminib-failed CML-CP and Ph+ ALL”) in this section “Key Clinical Results” include data from trials conducted outside of the United States. To the extent the trials were conducted outside of the United States, the FDA may not accept such data, and additional trials may be required, resulting in additional time and cost.

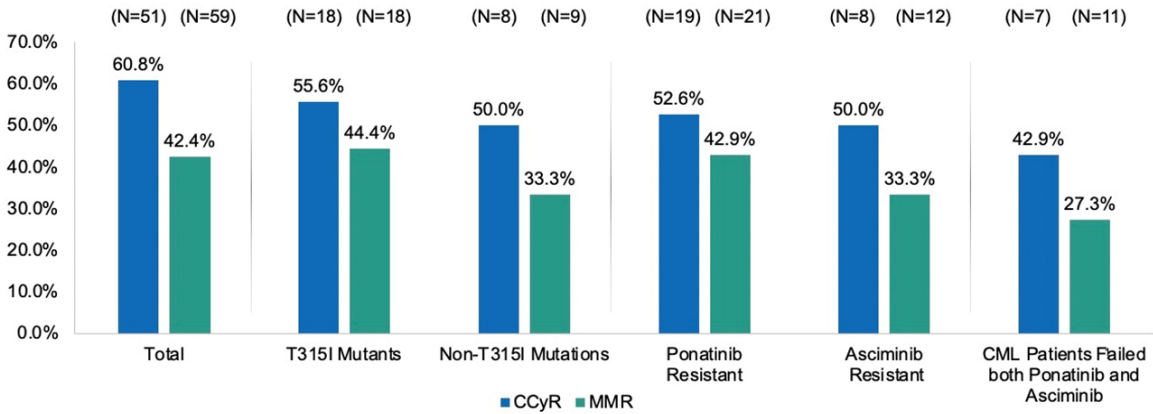
1. Strong antileukemic activity in Heavily Pretreated CML-CP Patients

Updated results from a phase 1b randomized clinical trial of Olverembatinib for the treatment of patients with CML or Philadelphia chromosome-positive ALL. In this trial, Olverembatinib had a favorable pharmacokinetic profile, was generally well tolerated, and showed strong antileukemic activity in patients with heavily pretreated chronic-phase CML with or without T315I variants, including prior ponatinib and/or asciminib failure. Olverembatinib may provide a viable new treatment option for patients after failure of 2 or more TKIs.

This multicenter phase 1b randomized clinical trial was conducted from January 28, 2020, to January 2, 2024, with a median (range) follow-up of 48 (0-166) weeks. Patients with CML or Philadelphia chromosome-positive ALL were enrolled. This bridging study was performed in part to confirm that there are no racial differences in the pharmacokinetic profile of Olverembatinib. Patients were randomly assigned to 30, 40, or 50 mg of Olverembatinib orally every other day in 28-day cycles.

Demographic. Of 80 included patients, 46 (58%) were male, and the median (range) age was 54.0 (21-80) years. The median (range) time from the initial diagnosis of CML or advanced Philadelphia chromosome-positive leukemia to the first dose of Olverembatinib was 5.9 (0.4-24.0) years. The study population was heavily pretreated: 14 (17.5%), 22 (27.5%), and 43 (53.8%) had received 2, 3, or 4 or more prior TKIs, respectively. Five patients had prior allogeneic stem cell transplant. A total of 46 patients (58%) had received ponatinib and 25 (31%) had received asciminib. A total of 11 patients had treatment failure with both ponatinib and asciminib. A total of 25 patients (31%) had a T315I variant at baseline. Among the 18 patients in the advanced leukemia group, 9 were in accelerated-phase CML, 6 in blast-phase CML, and 3 had Philadelphia chromosome-positive ALL.

Strong antileukemic activity in patients with heavily pretreated CML-CP, including T315I mutations, and Ponatinib and/or Asciminib failures



Efficacy results. Among evaluable patients with chronic-phase CML, CCyR occurred in 61% patients; MMR occurred in 42% of patients. Cytogenetic and molecular responses were similar in patients with or without T315I variants. A total of 58% of patients with prior ponatinib treatment achieved CCyR, and 37% achieved MMR. A total of 50% patients with asciminib resistance had CCyR, and 33% had MMR.

Safety results. Based on investigators’ assessments, 75% of patients experienced at least 1 treatment-related adverse event; 40% of patients experienced grade 3 or higher treatment-related adverse events; and 15% of patients experienced treatment-related serious adverse events, none of which were fatal. Frequently reported (10% or more) treatment-emergent adverse events included elevated blood creatine phosphokinase (all grades, 31 [39%]; grade 3 or higher, 10 [13%]) and thrombocytopenia (all grades, 23 [29%]; grade 3 or higher, 14 [18%]).

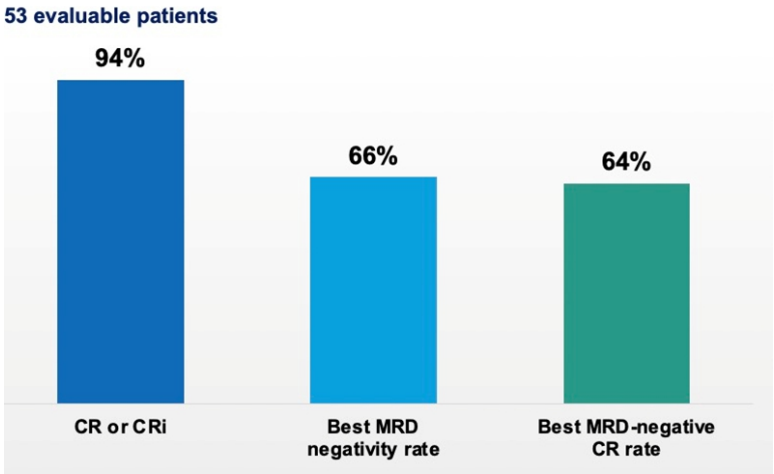
2. POLARIS-1 Global Phase III Part 1 Results - Olverembatinib + Low-intensity Chemotherapy in first-line Ph+ ALL

Updated results from POLARIS-1 (NCT06051409), a global registrational Phase III study designed to evaluate the efficacy and safety of Olverembatinib combined with low-intensity chemotherapy in patients with first-line Ph+ ALL. The primary endpoint of the study was MRD (BCR-ABL/ABL1 $\leq$ 0.01% by qPCR) negativity rate by the end of three induction cycles.

In patients with ND Ph+ ALL, Olverembatinib in combination with chemotherapy demonstrated an MRD-negative CR rate of 64.2% by the end of the induction therapy and a favorable safety profile.

Demographic. As of July 18, 2025, a total of 55 patients with first-line Ph+ ALL were enrolled in Part 1, including Olverembatinib 40 mg QOD (n = 15) and Olverembatinib 30 mg QOD (n = 40). The chemotherapy backbone consisted of 49 patients who received Olverembatinib + VD and 6 patients who received Olverembatinib + VDP. At baseline, the median age of the 55 enrolled patients was 43.0 years (range, 18–70), with 63.6% female and 36.4% male patients. Most patients were Asian (90.9%), while 9.1% were White. The BCR::ABL1 subtype distribution was predominantly P190 (65.5%), followed by P210 (29.1%), with smaller proportions of P190+P210 (3.6%) and P230 (1.8%). The mean treatment duration of all patients in Part A was 9.6 months.

Primary Endpoint: MRD Negativity Rate by the End of Three Induction Cycles



Efficacy results. As of July 18, 2025, among 53 efficacy-evaluable patients, 50 (94.3%) achieved a CR or CR with incomplete hematologic recovery by the end of induction therapy. The best MRD negativity and MRD-negative CR rates were 66.0% and 64.2%, respectively.

IKZF1plus (particularly with concurrent BTG1 deletion) is a widely recognized high-risk factor associated with poor prognoses in B-cell ALL (B-ALL) because it can often cause resistance to chemotherapies and a high propensity to relapse. Among the 10 patients in this study who had this genotype, the molecular response rate at the end of the induction therapy was 90% (9/10).

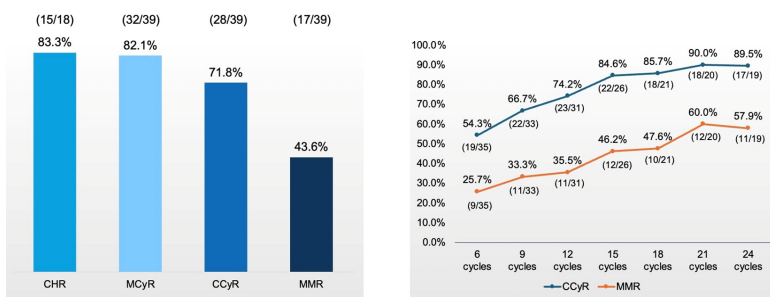
Safety results. Olverembatinib in combination with low-dose chemotherapy was well tolerated. Common (incidence >15%) grade $\geq$ 3 treatment-emergent adverse events (TEAEs) were neutropenia (63.6%), thrombocytopenia (56.4%), leukopenia (54.5%), anemia (49.1%), pneumonia (30.9%), hypokalemia (20%), and abnormal hepatic function (16.4%).

3. Olverembatinib as a viable 2L Treatment for CML-CP

This was an open-label, single-arm, multicenter investigator-initiated clinical study (ChiCTR2200061655) designed to evaluate the efficacy and safety of orally administered Olverembatinib at 40 mg every other day (QOD) in Chinese patients with CP-CML resistant/intolerant to one prior line of TKIs (including imatinib, flumatinib, nilotinib, and dasatinib) without the T315I mutation.

Demographics. As of July 24, 2025, the study had enrolled 47 patients with CP-CML without the T315I mutation. (93.6% first-line TKI-resistant, 6.4% first-line TKI-intolerant). The median age was 42.0 years, and 66.0% of patients were men. The median (range) interval from diagnosis to initial Olverembatinib treatment was 1.03 years. A total of 25.5% of patients had received 1L imatinib, and 74.5% of patients had been treated with a 1L 2G TKI, including dasatinib (n = 7, 14.9%), nilotinib (n = 13, 27.7%), or flumatinib (n = 15, 31.9%). A total of 76.6% of patients had no mutations at baseline, while 23.4% had non-T315I BCR::ABL1 kinase domain mutations.

72% CCyR and 44% MMR in efficacy-evaluable patients, increasing response over time



Efficacy results. As of July 24, 2025, 39 (83.0%) patients received at least one efficacy evaluation; 36 (76.6%) at least two efficacy evaluations; and 34 (72.3%) at least three efficacy evaluations. Two patients had not yet received their first efficacy evaluation.

As of the data cut-off date, 71.8% (28/39) of patients had achieved a CCyR and 43.6% (17/39) MMR. CCyR and MMR rates assessed at the end of cycles 6, 9, 12, 15, 18, 21, and 24 were 54.3% and 25.7%, 66.7% and 33.3%, 74.2% and 35.5%, 84.6% and 46.2%, 85.7% and 47.6%, 90.0% and 60.0%, and 89.5% and 57.9%, respectively, suggesting that responses deepened as treatment persisted.

Among 39 efficacy-evaluable patients, 30 received second-generation TKIs in first-line treatment. Of them, 76.7% (23/30) achieved a CCyR and 43.3% (13/30) MMR. Among the 9 patients who were pretreated with imatinib, 55.6% (5/9) achieved a CCyR and 44.4% (4/9) MMR.

Safety results. The median (range) treatment duration was 16.0 (1-18) cycles. A total of 42 (89.4%) patients experienced treatment-related adverse events (TRAEs) of any grade, including 21 (44.7%) patients who experienced grade ≥3 TRAEs and 6 (12.8%) patients who experienced serious adverse events (SAEs) related to Olverembatinib. Grade ≥3 hematologic toxicities included platelet count decreased (42.6%), neutrophil count decreased (25.5%), and anemia (8.5%). Olverembatinib-related SAEs included platelet count decreased (6.4%) and anemia, myelosuppression, and pyrexia (2.1% each). No deaths were reported during the study.

4. Olverembatinib Efficacy in MLN-FGFR1 Mutant Patients

This was a phase 2, open-label, multicenter investigator-initiated study that was performed to evaluate the efficacy and safety of Olverembatinib in adults with first-line or relapsed MLN-FGFR1. In this trial, Olverembatinib was highly effective and well tolerated in patients with MLN-FGFR1 in both preclinical and clinical settings. Combined chemotherapy was preferable in patients with BP disease, and allo-HSCT remained an important strategy for extending survival.

Demographics. As of October 30, 2025, 20 patients from 16 centers were enrolled and 17 patients were evaluated for efficacy. Median(range) age was 48(25-81) years old, 7 patients were men,14 had CP disease (10 with EMD, mostly presented as T-LBL) , 5 had BP disease (2 B-ALL, 2 AML and 1 MPAL) , 1 EMD only, 6 were previously treated 2 had prior alloHSCT,13 had peripheral blood eosinophilia, of whom 11(84.6%) had CP disease. ZMYM2 (65.0%) was the most observed fusion partner.RUNX1 mutation was detected in 9/16 (56.2%) patients.

Two-month and best response of olverembatinib in MLN-FGFR1					
Pt no.	Response at 2 months	Best response	Allo HSCT	Status	Relapse-free survival (mo.)
Pt01	CR	CMR	YES	Alive	38
Pt02	CR	CCyR	YES	Alive	28
Pt03	CRh	CRh	NO	Death(Infection)	3
Pt04	CR(CCyR)	CMR	YES	Alive	33
Pt05	PR	CCyR	YES	Death(Infection)	6
Pt06	CR	CMR	YES	Alive	24
Pt08	CR(CMR)	CMR	NO	Alive	18
Pt09	CR	CR	NO	Alive	10
Pt10	CHR	CHR	NO	Death(PD)	2
Pt11	CR	CR	NO	Alive	15
Pt12	PR	CR	NO	Alive	12
Pt13	PR	CCyR	NO	Death(PD)	6
Pt14	CR	CCyR	NO	Alive	12
Pt15	PR	CR	NO	Alive	11
Pt16	CR	CR	NO	Alive	8
Pt17	CR(CMR)	CMR	NO	Alive	7
Pt18	CR	CR	NO	Alive	3

Efficacy results. 13/17 (76.5%) patients achieved CR/CRh/CHR, among whom 1 achieved CCyR and 2 achieved CMR at 2 months’ evaluation. Best responses were 5 CMR, 4 CCyR, 8 CR/CHR. With a median (range) follow-up of 11 (2-38) months, 11 patients were still alive with no detected disease. Among the 5 patients who had received HSCT, 3 were in CMR to date, 1 relapsed, 1 died of transplant-related infection.

Safety results. Adverse events in 11 CP patients who were treated with Olverembatinib alone were evaluated. 1 patient reported grade 3 platelet count decrease and 1 patient reported grade 3 alanine aminotransferase elevation, hyperpressure cerebral infarction. Rash and constipation were mostly commonly observed.

5. Deep Remission, Improvement in Allo-HSCT Outcomes in Blast Crisis

This real-world practice analysis captured data from consecutively enrolled BC-CML patients aged ≥14 years undergoing allo-HSCT at the Institute of Hematology and Blood Diseases Hospital Chinese Academy of Medical Sciences between November 2021 and January 2025, including both de novo and chronic phase-transformed cases.

This real-world analysis provides the first clinical evidence supporting the efficacy and safety of Olverembatinib in transplant-eligible BC-CML. Olverembatinib significantly enhances pre-transplant molecular responses, compared to 1/2G-TKIs, associating with improved survival and reduced NRM in BC-CML patients receiving allo-HSCT. With a manageable safety profile, Olverembatinib represents a promising bridging strategy prior to allo-HSCT, potentially redefining frontline management of BC-CML.

Demographics. A total of 64 patients with BC-CML receiving pre-transplant TKIs treatment were included in the study (median age 33 years, range 14–61). At BC diagnosis, 43.8% (n=28) exhibited additional cytogenetic abnormality, including 20 complex karyotypes. Twenty patients (31.3%) harbored ABL1 mutations, predominantly E255K and Y253K. T315I was seen in 5 cases. Thirty (46.9%) patients carried additional genetic mutations, including myeloid neoplasm-associated mutations (e.g., ASXL1, RUNX1) and IKZF1 deletions. Extramedullary involvement occurred in 11 patients (17.2%). All patients received TKIs+chemotherapy before transplantation and were stratified by pre-transplant TKIs exposure: 1/2G-TKI cohort (n=42, imatinib, nilotinib, flumatinib or dasatinib) versus Olverembatinib (n=21, HQP1351), with balanced baseline characteristics.

	1/2G-TKI ² (N=42)	Olverembatinib (N=21)
Pre-transplantation treatment responses		
Hematologic remission rates	81%	100%
CCyR rate	55.8%	76.2%
Molecular remission at transplantation		
MMR	16.3%	61.9%
CMR	4.7%	23.9%
Survival outcomes		
2-year OS	57.2%	87.1%
2-year PFS	52.6%	75.8%
Non-relapse mortality	34.0%	12.9%
Relapse incidence	19.3%	12.5%

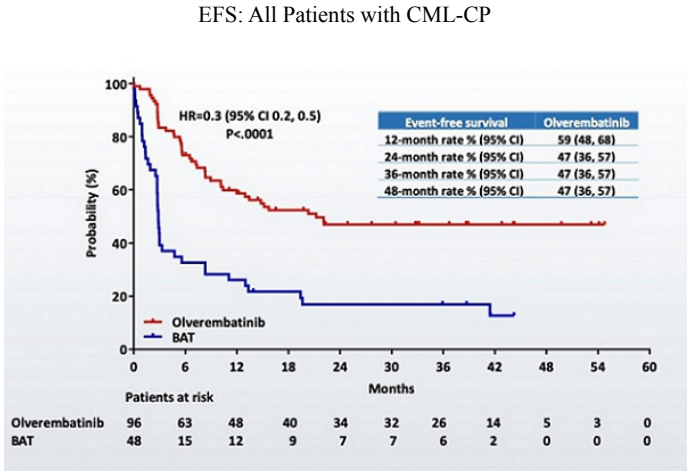
Efficacy results. The Olverembatinib cohort demonstrated advanced pre-transplantation treatment responses: higher hematologic remission rates (100% vs 81%, p<0.05) and CCyR rate (76.2% vs 55.8%, p=0.17). Notably, Olverembatinib achieved significantly improved molecular remission at transplantation: MMR 61.9% vs 16.3% (p<0.001) and CMR 23.9% vs 4.7% (p<0.05). Olverembatinib cohort showed clinically meaningful improved survival, including trends toward improved two-year OS (87.1% vs 57.2%) and two-year PFS (75.8% vs 52.6%),

Safety results. Safety analysis revealed treatment-related adverse events in Olverembatinib cohort 52.4% (11/21) of patients. Six (28.6%) developed grade 3/4 neutropenia. Cardiovascular Events were observed in two patients, including deep vein thrombosis (n=1) and pericardial effusion (n=1).

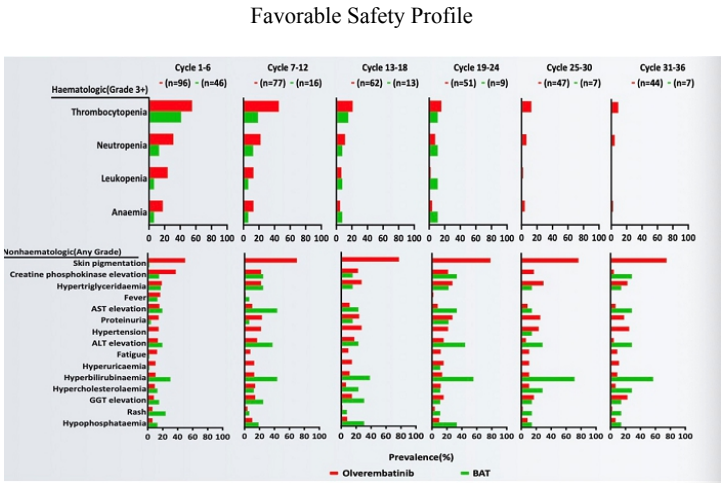
6. Registrational Phase II Study in CML-CP: 4-Year Follow Up

This was an open-label, randomized controlled, multicenter, pivotal registrational Phase II study (NCT04126681) designed to evaluate the efficacy and safety of Olverembatinib in patients with CML-CP resistant and/or intolerant to first- and second-generation TKIs. This report features an update on results released in an oral presentation at ASH 2023. In this trial, Olverembatinib demonstrated a clear therapeutic advantage over BAT in patients with CML-CP resistant and/or intolerant to first- and second-generation TKIs, including those without the T315I mutation.

Demographics. As of January 13, 2025, a total of 144 patients with CML-CP were enrolled in the study, including 105 patients without the T315I mutation. In this study, patients were randomized in a 2:1 ratio to the Olverembatinib arm or the control arm with investigators’ choices of best available treatment (BAT). The primary endpoint was event-free survival (EFS). An event was defined as disease progression; loss of achieved complete hematologic response (CHR), major cytogenetic response, or complete cytogenetic response (CCyR); treatment failure; no achieved CHR within 3 cycles; death from any cause; or unacceptable toxicity.



Efficacy results. The Olverembatinib arm achieved a significantly longer EFS than the BAT arm: among all patients with CML-CP, the median EFS of the Olverembatinib arm and the BAT arm were 21.2 months and 2.9 months ($P < 0.0001$), respectively. Among patients with CML-CP without the T315I mutation, the median EFS of the Olverembatinib arm and the BAT arm were 11.9 months and 3.1 months ($P = 0.0159$), respectively. Other efficacy parameters of the Olverembatinib arm were significantly better than those of the BAT arm: among all patients with CML-CP, CHR rates of the Olverembatinib arm and the BAT arm were 85% and 35%; CCyR rates were 38% and 19%; and major molecular response (MMR) rates were 30% and 8%, respectively. Among patients with CML-CP without the T315I mutation treated in the Olverembatinib arm or the BAT arm, CHR rates were 82% and 50%, CCyR rates 26% and 21%, and MMR rates 16% and 10%, respectively.



Safety results. Olverembatinib showed a favorable safety profile in patients with CML-CP with/without the T315I mutation, with no new safety signals. Grade ≥ 3 adverse events included hematologic toxicities. Notably, the incidence rate of vascular occlusion in the Olverembatinib arm was 7%.

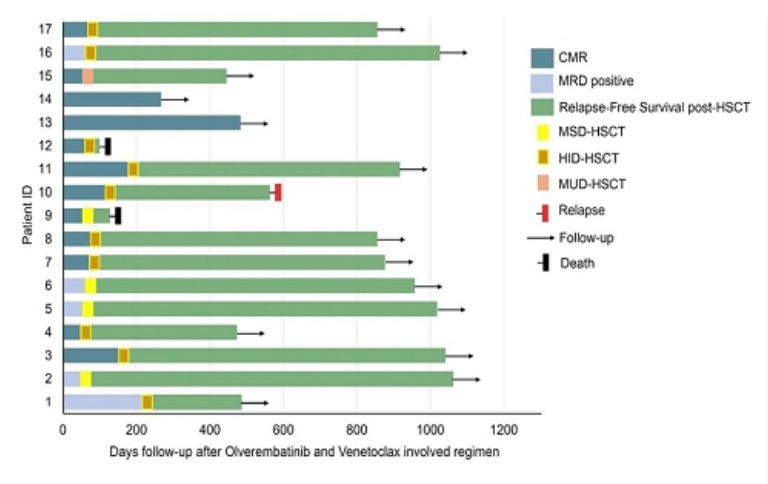
7. Olverembatinib + Bcl-2i Bridging: Potential for Chemo- or Immunotherapy Free Regimen with Lisoftoclax

This study aimed to investigate the efficacy and safety of an Olverembatinib-venetoclax regimen before bridging to HSCT in adult Ph/BCR-ABL1+ALL patients with refractory/relapsed disease or persistent MRD. This study demonstrated that the use of Olverembatinib-venetoclax involved regimen prior to transplantation is effective and safe. Prompt allo-HSCT bridging post-Olverembatinib-venetoclax treatment significantly enhances long-term outcomes in high-risk patients. Moreover, the results support the Olverembatinib-venetoclax involved regimen as a frontline consolidation or induction treatment, which may achieve rapid molecular remission, reduce pre-transplant treatment cycles, and minimize chemotherapy-related toxicity.

Demographics.

This single-center case series included 17 refractory/ relapsed (R/R) (n=2) and minimal residual disease (MRD) persistent positive (n=15) Ph+ALL patients who were treated with Olverembatinib-related therapy between February 20, 2022, and January 31, 2023, including 2 with hematology relapse, 9 with persistent positive MRD, and 1 with relapsed MRD. Four patients harbored a T315I mutation. Two patients had received prior blinatumomab or INO treatment. All patients had previously failed TKI treatment, with four of them who did not respond to at least two different TKIs. The median number of chemotherapies courses before enrollment was 3 (range: 3–11). The regimen included Olverembatinib (40 mg QOD) combined with venetoclax (100 mg d1, 200 mg d2, 400 mg, d3–28) + prednisone (1 mg/kg, d1 ~ 14) + vincristine (1.5 mg/m2, d1, d8) regimen. The last follow-up date was April,2025.

Olverembatinib + Venetoclax Combination: High Percentage of Relapse-Free Survival post-HSCT



Efficacy results. The median number of Olverembatinib + venetoclax regimen cycles was 2 (range, 1–3 cycles). With a median follow-up of 856-day post-HSCT, the 2-year overall survival and relapsed free survival rates was $88.2 \pm 7.8\%$ and $79.4 \pm 10.9\%$, respectively. 15 (83.3%) enrolled patients successfully underwent bridged allo-HSCT. Overall, all 2/2 patients with hematological recurrence achieved CMR, and 10 of the 15 MRD + patients achieved CMR, resulting in an overall CMR rate of 70.6%. Three patients who failed MRD clearance after one cycle of Olverembatinib and venetoclax regimen proceeded to the CD19 bispecific T-cell Engager (Blinatumomab, BiTE) therapy and only one attained MRD clearance. Notably, all patients with T315I mutations (4/4) achieved CMR before transplantation.

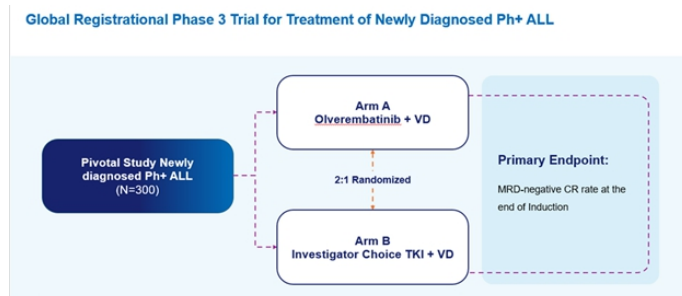
Safety results. Olverembatinib-venetoclax involved regimen demonstrated favorable tolerance and safety. Gastrointestinal symptoms were observed in one patient, while another experienced dizziness. Nine patients experienced grade 1–2 neutropenia and thrombocytopenia. No cardiovascular events, proteinuria, creatine kinase (CK) increase, rash, hypertension, or infection were observed. All patients completed the treatment, and there were no cases of treatment suspension or discontinuation owing to drug intolerance.

Olverembatinib Registrational Trials

We are currently conducting an FDA and EMA cleared registrational Phase 3 trial, or POLARIS-2, of Olverembatinib as a monotherapy for CML. We are also pursuing label expansion of Olverembatinib in an FDA and EMA cleared registrational Phase 3 trial, or POLARIS-1, in combination with chemotherapy for the treatment of frontline Ph+ ALL and another registrational Phase 3 trial, or POLARIS-3, as a monotherapy for SDH-deficient GIST.

POLARIS-1—Registrational Phase 3 trial for the treatment of first-line Ph+ ALL

In July 2023, we received clearance from the CDE to initiate our registrational Phase 3 trial (NCT06051409) of Olverembatinib in combination with chemotherapy in patients with first-line Ph+ ALL, or POLARIS-1, which may potentially make Olverembatinib the first TKI for frontline treatment of Ph+ ALL. In December 2025, we received clearance from the FDA and EMA.

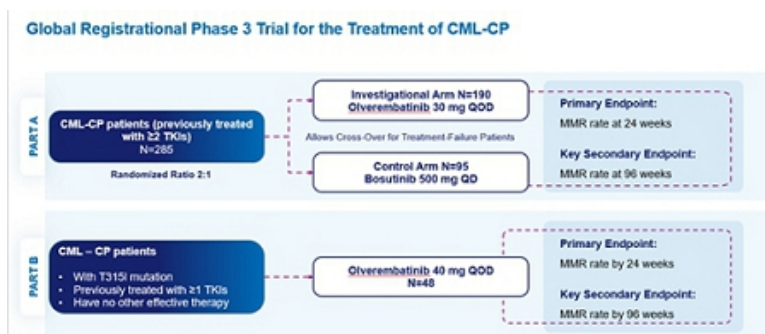


The POLARIS-1 trial is a global, multicenter, randomized controlled, open-label Phase 3 study designed to evaluate the efficacy and safety of Olverembatinib in combination with chemotherapy in first-line patients with Ph+ ALL. The POLARIS-1 study was also initiated in China after it was cleared by the China CDE in 2023. The primary endpoint will be MRD-Negative CR rate at the end of the third 28-day cycle.

We are continuing to enroll patients in POLARIS-1, and we plan to complete the majority of enrollment in 2026.

POLARIS-2—Registrational Phase 3 trial for the treatment of CML-CP

In February 2024, we received clearance from the FDA to initiate our registrational Phase 3 trial (NCT06423911) of Olverembatinib in CML-CP, both with and without *T315I* mutations, or POLARIS-2, the first registrational Phase 3 trial for Olverembatinib in patients with CML-CP to be conducted, and we are pursuing clearance in multiple countries. The POLARIS-2 protocol was submitted under an existing IND that was initially submitted to the FDA on June 10, 2019.



Our multi-center, randomized, open-label, registrational Phase 3 trial has two parts. Part A is a randomized controlled study that evaluates the efficacy and safety of Olverembatinib (investigational arm) compared to the efficacy and safety of bosutinib (control arm) in patients with CML-CP previously treated with at least two TKIs. Part B is a single arm study to evaluate the efficacy and safety of Olverembatinib in patients with CML-CP with *T315I* mutations previously treated with at least one TKI and without other available effective treatment options.

The primary endpoint for both parts is MMR rate at 24 weeks, and the key secondary endpoint is MMR rate at 96 weeks.

We are continuing to enroll patients in POLARIS-2, and we plan to advance enrollment of POLARIS-2 trial in 2026.

POLARIS-3—Registrational Phase 3 trial for SDH-deficient GIST

In May 2024, we received clearance from the CDE to initiate our registrational Phase 3 trial of Olverembatinib in patients with SDH-deficient GIST, or POLARIS-3, and we are pursuing clearance in multiple countries.



Our multi-center, randomized, open-label, registrational Phase 3 trial evaluates the efficacy and safety of Olverembatinib in patients with SDH-deficient GIST who have undergone previous treatment. Adult patients will receive 40 mg of Olverembatinib once every other day for 28 days.

The primary endpoint will be PFS rate at 13 months as evaluated by an independent review committee. Key secondary endpoints include CBR, overall response rate, time to relapse, duration of response, and OS.

We are continuing to enroll patients in the POLARIS-3 trial throughout 2026.

Our second lead asset: Lisaftoclax

Our second lead asset, Lisaftoclax, is a novel, oral Bcl-2 inhibitor developed to treat a variety of hematologic malignancies and solid tumors by selectively blocking Bcl-2 to restore the normal apoptosis process in cancer cells. In July 2025, Lisaftoclax was approved by China’s NMPA for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy, including BTK inhibitors, which makes Lisaftoclax the first Bcl-2 inhibitor receiving conditional approval and marketing authorization for the treatment of patients with CLL/SLL in China as well as the second Bcl-2 inhibitor approved globally. Shortly after the approval, we have commenced the commercial sales of Lisaftoclax in China. We believe that Lisaftoclax, with its short half-life and potential for patient-friendly ramp-up schedule, has the potential to serve as a backbone molecule for combination therapies to treat many hematological malignancies, including and beyond CLL/SLL. Furthermore, FDA has granted five ODDs to Lisaftoclax, including CLL and AML.

In addition to the registrational Phase 2 trial for which we have submitted an NDA that was accepted with priority review by the CDE, we are currently conducting an FDA and EMA cleared registrational Phase 3 trial, or GLORA, of Lisoftoclax in combination with BTK inhibitors for patients with CLL/SLL previously treated with BTK inhibitors for more than 12 months with suboptimal responses. Also, we are evaluating Lisoftoclax in combination with AZA in GLORA-4, an FDA and EMA cleared registrational Phase 3 trial, as a frontline treatment for high-risk MDS. In addition, we are pursuing approval of Lisoftoclax in combination with acalabrutinib as the frontline treatment for CLL/SLL in an FDA and EMA registrational Phase 3, or GLORA-2, trial. We are also evaluating Lisoftoclax in combination with AZA in GLORA-3, a registrational Phase 3 trial, as a frontline treatment for AML. Other clinical trials of Lisoftoclax are ongoing for MM and other hematological malignancies.

Summary of key completed and ongoing clinical trials for Lisoftoclax

Clinical Program	Indication	Dose Escalation/ Dose Expansion	Clinical POC	Registrational Trial	Marketed
Pivotal Ph-II	CLL/SLL ¹	Single agent		Approved in China 2025	
GLORA	CLL/SLL sub-optimal BTK response (Add-on)	+ BTK Inhibitor	FDA, EMA, and CDE cleared	Global Phase III Registrational Trial	
GLORA-2	First-Line CLL/SLL	+ acalabrutinib	EMA and CDE cleared	Multinational Phase III Registrational Trial	
GLORA-3	First-Line Elderly and Unfit AML	+ AZA (azacitidine)	EMA and CDE cleared	Multinational Phase III Registrational Trial	
GLORA-4	First-Line HR-MDS	+ azacitidine	FDA, EMA, and CDE cleared	Global Phase III Registrational Trial	

Note:

¹ In July 2025, Lisoftoclax was approved by NMPA in China for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy including BTK inhibitors.

Current treatment paradigm and its limitations

CLL/SLL

Current treatments for CLL include chemotherapy, anti-CD20 mAb, BTK inhibitors, PI3K inhibitors, and Bcl-2 inhibitors. The frontline standard of care is either rituximab or an obinutuzumab/chemotherapy combination or ibrutinib, a BTK inhibitor. The FDA approval of idelalisib, a PI3K inhibitor, and venetoclax, a Bcl-2 inhibitor, have provided new options to treat R/R CLL. In May 2019, the FDA granted approval on the combination of venetoclax and obinutuzumab for the frontline treatment of patients with CLL/SLL. To date, venetoclax is not approved for CLL/ SLL in China. CLL/SLL still presents major clinical challenges and urgent medical needs for new treatment options that can offer both efficacy and safety. There is increasing evidence that a double combination of CD20 or BTK with a Bcl-2 targeted agent may offer deeper and more durable remission of an MRD negative response.

Bcl-2 is highly expressed in all CLL cells in all patients, and a great majority of CLL cells appear dependent on Bcl-2 for survival. Bcl-2 inhibitors are effective as a monotherapy in approximately 60 to 80% of patients with relapsed CLL, and CR, including CR with incomplete recovery, or CRi, can be expected in 15% to 20% of patients. The rate of response, including CR, is independent of genetic subtypes, but the negative prognostic genetic markers del17p, TP53 and NOTCH1 mutations are associated with less durable responses per multivariable analyses. Achieving CR and/or having undetectable MRD in the peripheral blood (achieved in 30% of patients) or bone marrow is associated with prolonged remissions.

AML

The frontline treatment for AML generally involves the use of cytarabine and daunorubicin/idarubicin as an induction therapy, followed by high dose cytarabine as a consolidation therapy. Combination regimens including FLAG-Ida, MEC, or hypomethylating agents are used in relapse cases. As of the date of this Annual Report on Form 20-F, there are several approved drugs on the market to treat a subset of AML that has mutations in the IDH2, FLT3 or CD33 genes in addition to several targeted drugs in clinical development for AML.

Bcl-2 is variably expressed in AML, and only a minority of patient samples show marked sensitivity. Consistent with this, single agent activity is evident in patients. Available clinical data reflect that inhibition of Bcl-2 in AML results in a “hammer-strike” effect, with Bcl-2 being a significant target, but not a bullseye. Consequently, combination therapy is essential. In relapsed AML, the CR/CRi rate appears higher with these combinations than with monotherapy. In October 2020, the FDA granted approval to venetoclax in combination with AZA, decitabine, or low-dose cytarabine for newly-diagnosed AML in adults who are 75 years or older, or who have co- morbidities precluding intensive induction chemotherapy.

MDS

Treatment for MDS varies depending on the clinical presentation and prognosis, as well as the patient’s age, health, prior treatments, and other factors. MDS may be treated with chemotherapy, growth factors (to support hematopoiesis), blood transfusions, and other supportive therapy, and stem cell transplantation. Lower-risk MDS may require only growth factors and/or transfusions. HR MDS is typically treated with DNA hypomethylating agents, such as AZA or decitabine. AZA has also been shown to improve survival in certain patients. Since HR MDS can progress to AML, it is often also treated with drug regimens used in AML. However, all patients eventually progress on these therapies. HSCT remains the only treatment for MDS with curative potential, but only a fraction of patients are eligible and/or receive a transplant. More so, HSCT is associated with considerable morbidity and mortality. There are a few advanced-stage clinical trials that are evaluating the potential of Bcl-2 inhibitor in the treatment of MDS, including the Phase 3 VERONA trial of venetoclax in combination with AZA to assess change in complete remission and overall survival in first-line patients with HR MDS, but as of the date of this Annual Report on Form 20-F, venetoclax has not received FDA approval for frontline treatment of patients with first-line HR MDS. Thus, there remains a great unmet need for more effective drug treatments for MDS.

Our solution: Lisoftoclax

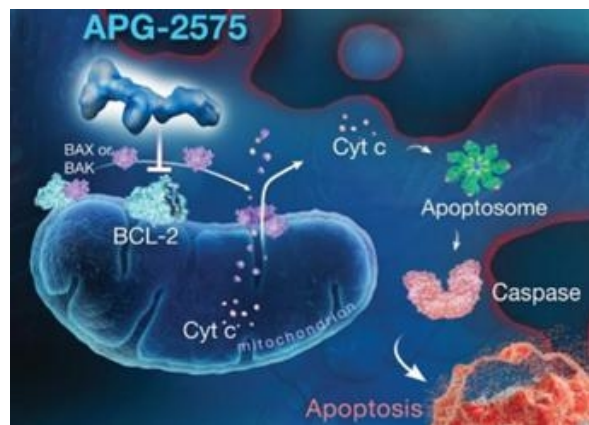
Our second lead asset, Lisoftoclax, is a novel Bcl-2 inhibitor that we are developing for the treatment of various hematological malignancies. In July 2025, Lisoftoclax was approved by China’s NMPA for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy, including BTK inhibitors, which makes Lisoftoclax the first Bcl-2 inhibitor receiving conditional approval and marketing authorization for the treatment of patients with CLL/SLL in China as well as the second Bcl-2 inhibitor approved globally. Shortly after the approval, we have commenced the commercial sales of Lisoftoclax in China.

Through the use of a classic rational design approach to the discovery of this candidate, Lisoftoclax demonstrates unique pharmacokinetic properties in the inhibition of its target. These properties include potent inhibition at the time of maximum concentration with limited persistence in plasma. In addition, the short ramp-up period for Lisoftoclax dosing provides potential advantages both for patients and the health care system.

Mechanism of action

The B-cell lymphoma 2, or Bcl-2, family is comprised of proteins that are highly involved in regulating apoptosis. All proteins belonging to the Bcl-2 family contain at least one more of four domains, called Bcl-2 homology, or BH, domains, and named BH1, BH2, BH3 and BH4, and some members, such as Bim, contain only a single BH3- domain. The anti-apoptotic proteins, including Bcl-2 and Bcl-x(L), inhibit cell death; in contrast, the pro-apoptotic proteins such as Bim is, promotes cell death. Lisoftoclax binds to the Bcl-2 and disrupts the Bcl-2-Bim complex, and therefore, Bim is released from the complex and activates apoptosis. Lisoftoclax also induces cellular apoptosis by disrupting Bcl-2/BH3 interactions, and indirectly neutralizing MCL-1 functions, leading to downstream caspase activation.

Mechanism of Action of Lisoftoclax



Key clinical results

- **Lisoftoclax shows strong clinical activity in AML and MDS and the potential to overcome Venetoclax resistance in AML**, see “*1. Lisoftoclax Shows Strong Clinical Activity in AML and MDS as well as in Venetoclax Refractory AML*”
- **Strong ORR (62.5%) in the challenging, BTKi-failed R/R CLL/SLL patients**, see “*2. Monotherapy in a Registrational Phase II Study of BTKi-failed R/R CLL/SLL Patients*”
- **Strong potential for combination with Olverembatinib in FLT3-ITD mutant AML, combination with Alrizomadlin (APG-115) to overcome venetoclax resistance in AML and combination with Alrizomadlin (APG-115) for Diffuse Large B-Cell Lymphoma (DLBCL)**, see “*3. Lisoftoclax – A Potential Cornerstone for Combination Drugs Across Multiple Diseases*”

Lisoftoclax also has a unique PK profile compatible with a potentially more convenient daily (vs. weekly) dose ramp-up schedule and induced rapid clinical responses in patients with CLL/SLL or other hematological malignancies. Previous clinical results showed Lisoftoclax achieved target treatment dose and BTK inhibitor combination in as quickly as approximately one week.

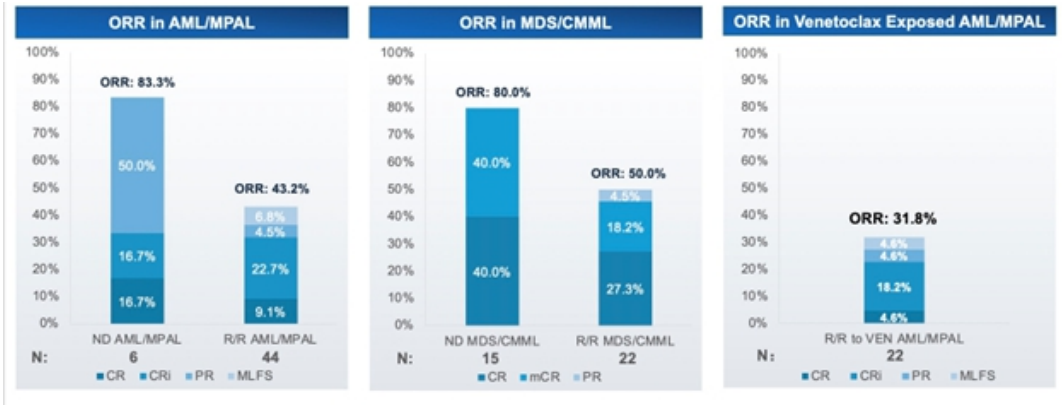
Additionally, Lisoftoclax in combination with Alrizomadlin has demonstrated further benefit in AML, with potential to overcome venetoclax resistant.

All of the results presented above and below in this section “*Key Clinical Results*” include data from trials conducted outside of the United States. To the extent the trials were conducted outside of the United States, the FDA may not accept such data, and additional trials may be required, resulting in additional cost and time.

1. *Lisaftoclax Shows Strong Clinical Activity in AML and MDS as well as in Venetoclax Refractory AML*

This was a phase Ib/II study (NCT04964518) designed to evaluate the efficacy and safety of Lisaftoclax in combination with AZA in patients with ND or relapsed/refractory AML, mixed-phenotype acute leukemia (MPAL), chronic myelomonocytic leukemia (CMML), or higher-risk (HR) MDS. The first part of this study was the dose-escalation phase, and the second part was the dose-expansion phase. These preliminary clinical data show that the combination regimen of Lisaftoclax plus AZA holds promise in overcoming venetoclax resistance, therefore potentially offering a new treatment option to patients with AML/HR MDS.

Demographics. As of July 1, 2025, 103 patients were enrolled, including 63 patients with AML/MPAL (of whom 56 had relapsed/refractory diseases) and 40 patients with HR MDS/CMML (of whom 25 had relapsed/refractory diseases).



Efficacy results. In the 44 evaluable patients with R/R AML/MPAL, the ORR was 43.2%, and the CR rate was 31.8% (14/44). In the 22 evaluable patients with venetoclax-exposed R/R AML/MPAL, the ORR was 31.8% (7/22), and the CR rate was 22.7% (5/22). In the 15 evaluable patients with ND HR MDS/CMML, the ORR was 80.0%, including 6 (40.0%) patients who achieved a CR, and 6 (40.0%) who achieved a marrow CR (mCR).

Median overall survival (OS) values for patients with R/R AML/MPAL or R/R HR MDS/CMML were 7.6 months and 11.3 months, respectively. The median OS was 6.3 months in patients with ND AML/MPAL and was not reached in patients with ND HR MDS/CMML.

Safety results. No dose-limiting toxicities (DLTs) were reported in part one for dose-escalation or part two for dose-expansion. Common grade ≥ 3 treatment-emergent adverse events (TEAEs) included neutropenia (41.7%), febrile neutropenia (35.0%), thrombocytopenia (26.2%), and anemia (17.5%).

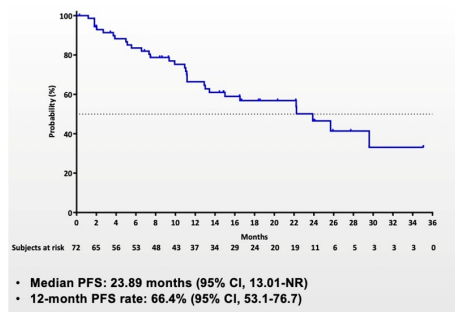
2. *Monotherapy in a Registrational Phase II Study of BTKi-failed R/R CLL/SLL Patients*

This was a pivotal registrational Phase II study (NCT05147467) in patients with CLL/SLL, with the objective response rate (ORR) as its primary endpoint. Patients in this study were refractory to, relapsed on, or intolerant of both BTK inhibitors and ICTs; or failed prior BTK inhibitors and were ineligible for ICTs. Lisaftoclax monotherapy demonstrated significant and durable clinical efficacy and a manageable safety profile in patients with heavily pretreated BTK-refractory R/R CLL/SLL, underscoring its utility as a potential new treatment option.

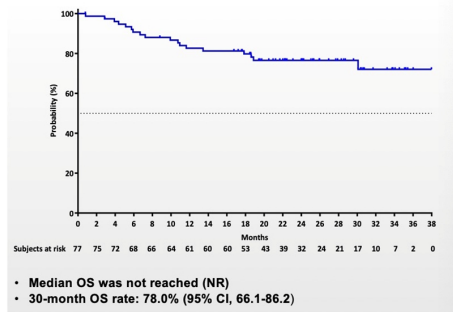
Demographics. A total of 77 patients were enrolled in this study. Among them, 33 (42.9%) had chromosomal complex karyotype, 30 (39%) had del(17p)/TP53 mutation, and 41 (53.2%) had unmutated IGHV. Among patients who had chromosomal complex karyotype, 63.6% had concurrent chromosomal complex karyotype and 63.6% had concurrent high karyotypic complexity (abnormal chromosome number ≥ 5).

Efficacy Assessment	R/R CLL/SLL
Evaluable patients (n)	72
Response, % (n) (Confirmed by the IRC)	
ORR	62.5% (45)
CR/CRi	4.2% (3)
PR	58.3% (42)
SD	30.6% (22)
PD	6.9% (5)
MRD in PB assessment, n	
MRD	21.8% (12)
MRD in BM assessment*, n	11
MRD	54.5% (6)
mDOR, mo. (95% CI)	18.53 (14.75-NR)
mPFS, mo. (95% CI)	23.89 (13.01-NR)
12-month PFS rate (95% CI)	66.4% (53.1-76.7)
mOR, mo. (95% CI)	NR ¹
30-month OS rate (95% CI)	78.0% (66.1-86.2)

Progression-free survival (PFS) by IRC



Overall survival (OS) by IRC

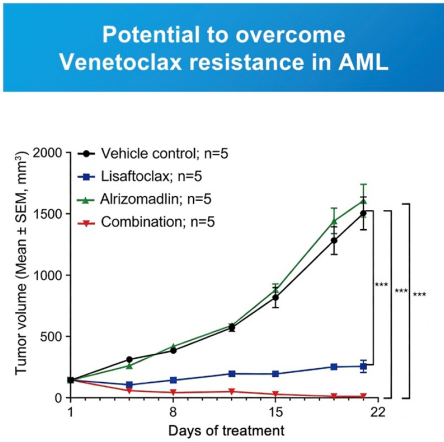


Efficacy results. As of July 25, 2025, among 72 evaluable patients with R/R CLL/SLL, the ORR as confirmed by the independent review committee (IRC) was 62.5%, the median progression-free survival (mPFS) was 23.89 months (with a median follow-up of 22.01 months). Among high-risk patients (those with adverse prognostic genotypes such as del(17p)/TP53 mutation, chromosomal complex karyotype, and unmutated IGHV), the treatment showed clinically meaningful deep responses. 21.8% of patients achieved minimal residual disease (MRD) negativity in peripheral blood. In the 11 evaluable patients with bone marrow MRD, 54.5% achieved bone marrow MRD negativity.

Lisaftoclax monotherapy demonstrated a median progression-free survival of 23.89 months in patients with heavily pretreated BTK-refractory R/R CLL/SLL, with no tumor lysis syndrome reported

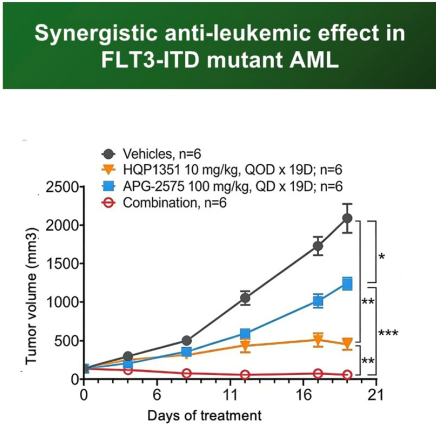
Safety results. Lisaftoclax demonstrated a manageable safety profile in BTKi-pretreated patients. Frequent grade ≥ 3 treatment-related adverse events were hematologic toxicities that included decreased neutrophil count, decreased platelet count, and anemia. Neither tumor lysis syndrome (TLS) nor treatment-related deaths occurred during the study.

3. Lisafoclax – A Potential Cornerstone for Combination Drugs Across Multiple Diseases



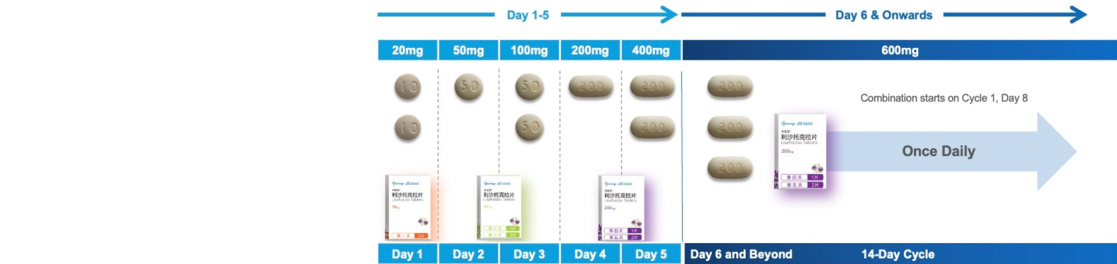
The data from a preclinical study demonstrated that Lisafoclax in combination with Alrizomadlin overcomes venetoclax resistance mediated by various mechanisms, including *BCL-2* mutations. In addition, we posit further, putative molecular mechanisms. Our data rationalize clinical development of this treatment combination in patients with diseases that are insensitive or resistant to venetoclax.

Results. The combination exhibited synergistic antiproliferative and apoptogenic activities in TP53 wild-type AML cell lines in vitro. This synergy was further exemplified by deep antitumor responses and prolonged survival in AML cell line–derived and patient-derived xenograft models. Interestingly, the combination treatment resensitized (to apoptosis) venetoclax-resistant cellular and mouse models established via chronic drug exposure or genetically engineered with clinically relevant *Bcl-2* gene mutations. Synergistic effects in reducing cellular viability and proliferation were also demonstrated in primary samples of patients with venetoclax-resistant AML treated with Lisafoclax and Alrizomadlin ex vivo. Mechanistically, Alrizomadlin likely primes cancer cells to *Bcl-2* inhibition-induced cellular apoptosis by downregulating expression of antiapoptotic proteins myeloid cell leukemia-1 and *Bcl-extra-large* and upregulating pro-death *Bcl-2*–associated X protein.



The data from a preclinical study demonstrated that FLT3 inhibition by HQP1351 downregulates MCL-1 and synergizes with *Bcl-2* inhibitor APG-2575 to potentiate cellular apoptosis in FLT3-ITD mutant AML. Our findings provide a scientific rationale for further clinical investigation of HQP1351 combined with APG-2575 in patients with FLT3-ITD mutant AML.

Results. HQP1351 potently induced apoptosis and inhibited FLT3 signaling in FLT3-ITD mutant AML cell lines MV-4-11 and MOLM-13. HQP1351 monotherapy also significantly suppressed growth of FLT3-ITD mutant AML xenograft tumors and prolonged survival of tumor-bearing mice. HQP1351 and APG-2575 synergistically induced apoptosis in FLT3-ITD mutant AML cells and suppressed growth of MV-4-11 xenograft tumors. Combination therapy improved survival of tumor bearing-mice in a systemic MOLM-13 model and showed synergistic anti-leukemic effects in a patient-derived FLT3-ITD mutant AML xenograft model. Mechanistically, HQP1351 downregulated expression of myeloid-cell leukemia 1 (MCL-1) by suppressing FLT3-STAT5 (signal transducer and activator of transcription signaling and thus enhanced APG-2575-induced apoptosis in FLT3-ITD mutant AML cells.



Differentiated trial design. Patients with first-line CLL/SLL or R/R CLL/SLL were treated daily with Lisafoclax alone or in combination with continuous acalabrutinib or rituximab for six 28-day cycles. Primary objectives were to determine the RP2D, safety and efficacy, including ORRs of Lisafoclax alone and combined with acalabrutinib or rituximab. Patients underwent Lisafoclax daily ramp-up over 4 to 6 days, with the monitoring of TLS as follows without debulking: 20 mg on day 1; 50 mg on day 2; 100 mg on day 3; 200 mg on day 4; and 400 mg on day 5. Dose ramp-up was followed by Lisafoclax target doses of 400, 600 or 800 mg. Patients in the combination groups also completed the daily ramp-up, as well as an additional 7 days of Lisafoclax at the target dose, acalabrutinib or rituximab was added on day 8, and then treated until disease progression or unacceptable toxicity was observed. The daily dose ramp-up is more convenient to healthcare professionals and patients because the therapeutic dose can be reached earlier, in this trial as early as day 8.

Lisafoclax registrational trials

We are currently conducting four pivotal registrational trials for Lisafoclax as a treatment for patients with CLL/ SLL that do not achieve CR from treatment with BTK inhibitors, or GLORA, which is cleared by the FDA, first-line CLL/SLL patients, or GLORA-2, first-line or elderly/unfit patients with AML, or GLORA-3, and first-line patients with HR MDS, or GLORA-4.

We previously completed a registrational Phase 2 trial for the treatment of R/R CLL/SLL in China, and Lisafoclax was approved by China’s NMPA for the treatment of adult patients with CLL/SLL who have previously received at least one systemic therapy including BTK inhibitors in July 2025.

Completed registrational Phase 2 trial for the treatment of R/R CLL/SLL in China

In December 2021, we received clearance from the CDE to initiate our registrational Phase 2 trial (NCT05147467) of Lisafoclax for the treatment of patients with R/R CLL/SLL in China.

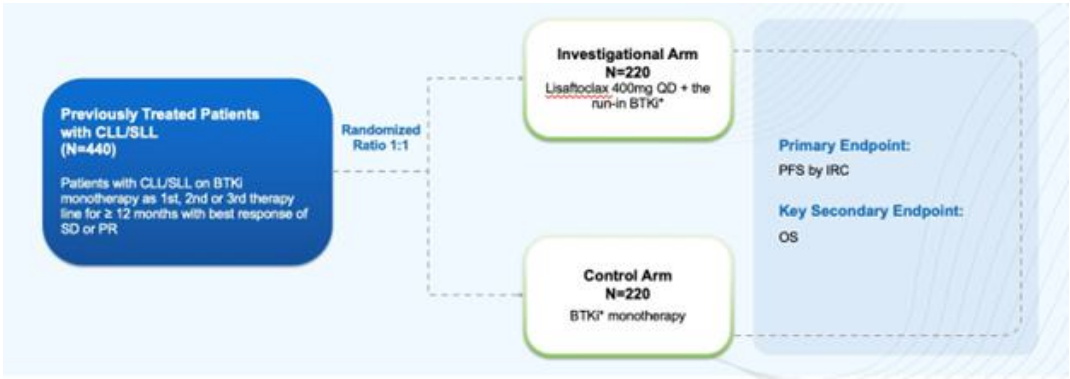
This is a single-arm, open-label, multi-center, registrational Phase 2 trial to evaluate the efficacy and safety of Lisafoclax as a single agent in patients with R/R CLL/SLL where we planned to enroll approximately 75 CLL/SLL subjects who have failed or are intolerant to prior BTK inhibitors and immunochemotherapy.

Eligible subjects received Lisafoclax 600 mg, administered orally once daily with repeated 28-day cycles.

The primary endpoint of this trial is ORR. Response is evaluated every two 8-week cycles till complete treatment or one month after last dose. Other endpoints include MRD and Bcl-2 expression.

GLORA—Registrational Phase 3 trial for the treatment of CLL/SLL with prior BTK inhibitors

In August 2023, we received clearance from the FDA to initiate a registrational Phase 3 clinical trial (NCT06104566) of Lisoftoclax in combination with BTK inhibitors for the treatment of patients with CLL/SLL previously treated with BTK inhibitors (GLORA). Since then, we have also received clearance to proceed with clinical trials in Australia, Canada, EU and UK, and we are pursuing clearance in multiple other countries. The protocol for this trial was submitted pursuant to an existing IND that was initially submitted to the FDA on December 22, 2017. This trial is currently being conducted in Australia, Canada, Japan, certain European countries, United Kingdom and the United States.



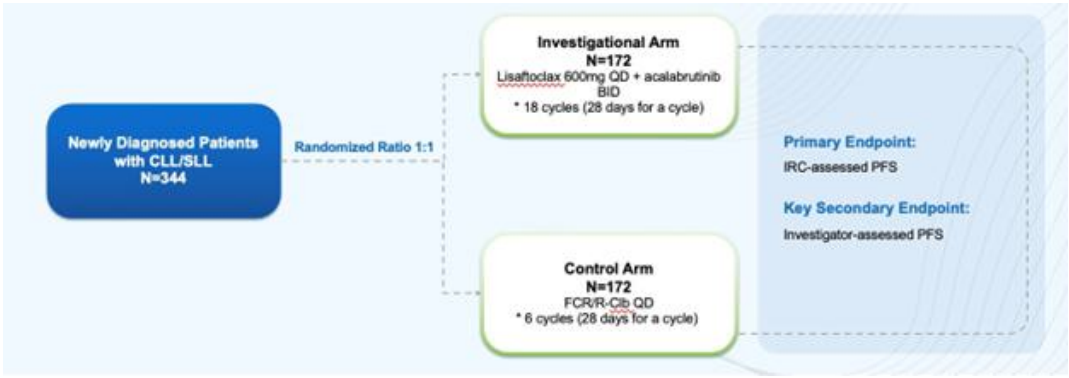
Our multi-center, randomized, controlled, registrational Phase 3 trial evaluates the efficacy and safety of Lisoftoclax in combination with a BTK inhibitor in patients with CLL/SLL previously treated with a BTK inhibitor monotherapy for more than 12 months with suboptimal responses.

In the investigational arm, patients will be dosed with Lisoftoclax in combination with a BTK inhibitor. In the control arm, patients will be dosed with a BTK inhibitor as a monotherapy. We are continuing to enroll patients for GLORA throughout 2026 with a target enrollment of 440 patients.

The primary endpoint of this trial is to evaluate the PFS of Lisoftoclax in combination with BTK inhibitors compared with BTK inhibitors as a monotherapy in patients with CLL/SLL previously treated with BTK inhibitors as determined by an independent review committee using the guidelines. The key secondary endpoint is OS.

GLORA-2—Registrational Phase 3 trial for frontline treatment in first-line CLL/SLL

In October 2023, we received clearance from the CDE to initiate our registrational Phase 3 trial (NCT06319456) of Lisoftoclax in combination with acalabrutinib in patients with first-line CLL/SLL, or GLORA-2, and we are pursuing clearance in multiple countries. This clearance could potentially pave the way for Lisoftoclax, in this combination regimen, to become a frontline treatment for CLL/SLL.

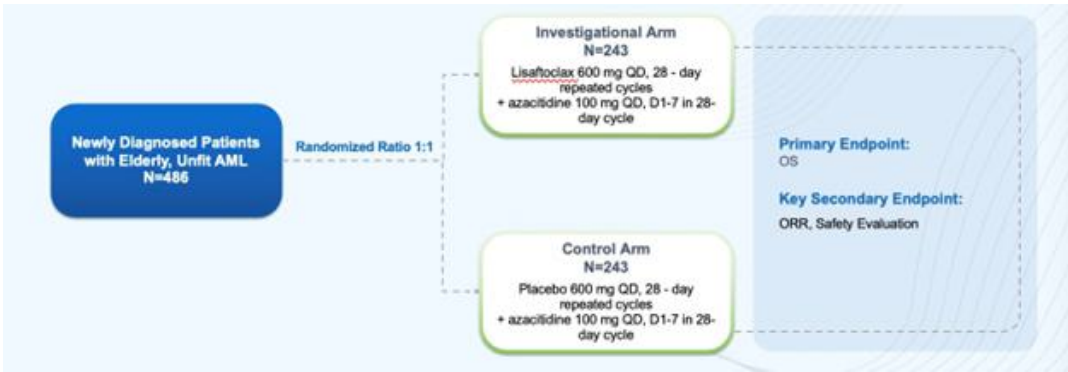


Our multi-center, randomized, open-label, registrational Phase 3 confirmatory trial designed evaluates the efficacy and safety of Lisoftoclax combined with acalabrutinib compared to the efficacy and safety of an immunochemotherapy (or cancer immunotherapy, or CIT) in patients with first-line CLL/SLL. We are continuing to enroll patients for GLORA-2 throughout 2026 with a target enrollment of 344 patients.

In the investigational arm, patients will be dosed with 20 mg to 600 mg of Lisoftoclax once daily with acalabrutinib twice a day for eighteen 28-day cycles. In the control arm, the CIT regimen includes fludarabine, cyclophosphamide, rituximab, and chlorambucil once daily for six 28-day cycles. The primary endpoint is PFS, which is defined as the time from randomization to disease progression or death from any cause, as determined by an independent review committee. The key secondary endpoint is investigator-assessed PFS.

GLORA-3—Registrational Phase 3 trial as frontline treatment for elderly/unfit patients with first-line AML

In December 2023, we received clearance from the CDE to initiate our registrational Phase 3 trial (NCT06389292) of Lisaftoclax in combination with AZA in elderly/unfit patients with first-line AML, or GLORA-3, and we are pursuing clearance in multiple countries. This clearance could potentially pave the way for Lisaftoclax, in this combination regimen, to become a frontline treatment for AML.



Our multi-center, randomized, double-blind, placebo-controlled, registrational Phase 3 trial evaluates the efficacy and safety of Lisaftoclax in combination with AZA compared to the efficacy and safety of a placebo in combination with AZA in first-line AML patients who are old or not eligible for standard induction chemotherapy.

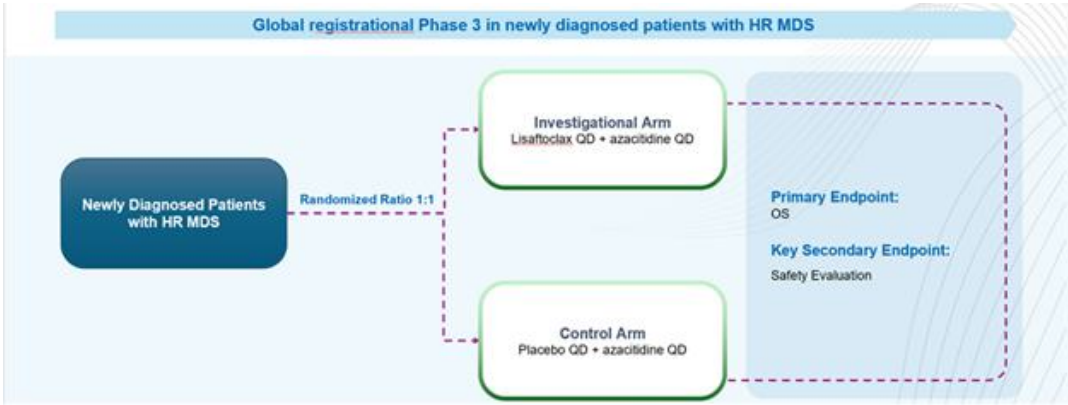
In the investigational arm, patients will be dosed daily with Lisaftoclax in combination with AZA for the first seven days of a 28-day cycle. In the control arm, patients will be dosed with placebo in combination with AZA for the first seven days of a 28-day cycle.

The primary endpoint is OS, defined as the time from the date of randomization to the date of death of any cause. The secondary endpoints include percentage of participants with ORR and safety evaluation.

We are continuing to enroll patients for GLORA-3 throughout 2026 with a target enrollment of 486 patients.

GLORA-4—Registrational Phase 3 trial as frontline treatment for first-line patients with HR MDS

In 2024 and 2025, we received clearance from the CDE and FDA to initiate our registrational Phase 3 trial (NCT06641414) of Lisaftoclax in combination with AZA in first-line patients with HR MDS, or GLORA-4, and we are pursuing clearance in multiple countries. This clearance could potentially pave the way for Lisaftoclax, in this combination regimen, to become a frontline treatment for HR MDS.



Our multi-center, randomized, double-blind, placebo-controlled, registrational Phase 3 trial, evaluates the efficacy and safety of Lisaftoclax in combination with AZA compared to the efficacy and safety of a placebo in combination with AZA in patients with first-line HR MDS.

In the investigational arm, patients will be dosed with Lisaftoclax in combination with AZA. In the control arm, patients will be dosed with placebo in combination with AZA. The primary endpoint is OS.

We are continuing to enroll patients in the GLORA-4 trial throughout 2026.

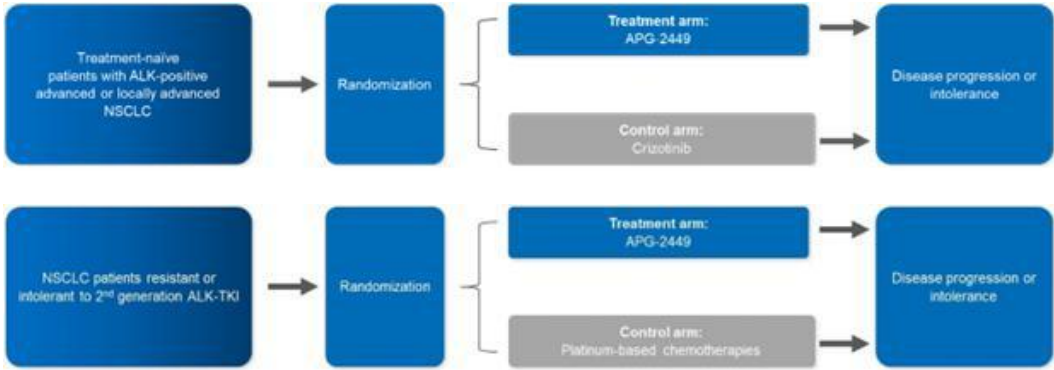
Our other clinical candidates

Compound	Target	Indication	Dose Escalation/ Dose Expansion	Clinical POC	Registrational Trial
APG-2449	FAK/ALK/ ROS1	NSCLC / Ovarian cancer			
Alrizomadlin (APG-115)	MDM2-p53	ACC, MPNST, AML/MDS, pediatric solid tumors			
Pelcitoclax (APG-1252)	Bcl-2/Bcl-xL	NSCLC, SCLC, neuroendocrine tumors, NHL			
APG-5918	PRC2 Inhibitor	anemia, oncology			
APG-3288	BTK Degradar	B-cell lymphoma			

APG-2449

APG-2449 is a novel, orally active, small-molecule focal adhesion kinase (FAK), the third generation of anaplastic lymphoma kinase (ALK) and receptor tyrosine kinase C-ros oncogene 1 (ROS1) triple ligase kinase inhibitor (TKI) designed and developed by Ascentage Pharma. It is the first FAK inhibitor approved by CDE for clinical study in China. In the first-in-human trial, cerebrospinal fluid PK analyses showed that APG-2449 was brain-penetrant. An updated study of APG-2449 demonstrated preliminary clinical benefit in patients with NSCLC whose disease was TKI naïve and resistant to 2G ALK inhibitors, especially in brain metastases. In addition, high pFAK expression levels in baseline tumor tissue correlated with improved APG-2449 treatment responses in patients with NSCLC resistant to 2G ALK inhibitors, suggesting that the increase of pFAK may be associated with second-generation ALK TKI resistance.

In October 2024, APG-2449 was cleared by the Center for Drug Evaluation (CDE) of China’s National Medical Product Administration (NMPA) to enter two registrational Phase III studies that will separately evaluate APG-2449 in patients with non-small cell lung cancer (NSCLC) who are resistant to or intolerant of second-generation anaplastic lymphoma kinase (ALK) TKIs; and treatment-naïve patients with ALK-positive advanced or locally advanced NSCLC.



A Phase 1b/2 study of APG-2449 in combination with liposomal doxorubicin hydrochloride in platinum-resistant ovarian cancer is ongoing.

Select clinical trial results

Non-small cell lung cancer (NSCLC)

This single-arm, multicenter, phase 1 clinical trial included a dose escalation to determine maximum tolerated dose (MTD) and recommended phase 2 dose (RP2D), followed by a dose-expansion stage at RP2D to evaluate safety. Secondary endpoints included pharmacokinetics, pharmacodynamics, and preliminary efficacy. APG-2449 was administered once daily in 28-day cycles through a 3 + 3 dose escalation.

Demographics. 144 patients were enrolled from May 27, 2019, to April 2, 2024, and received APG-2449 (150-1500 mg/day). Eligible patients were aged 18 years or older and had advanced ALK or ROS1 fusion gene-positive NSCLC and other solid tumors (during the dose escalation). Patients with ALK-positive or ROS1-positive NSCLC regardless of previous TKI treatment were enrolled during the dose escalation. After RP2D was determined, patients with second-generation TKI-treated ALK + NSCLC, TKI-naïve ALK +, and TKI-naïve or TKI-treated ROS1 + NSCLC were enrolled in dose expansion. Eligible patients also had: (1) an Eastern Cooperative Oncology Group performance status (ECOG PS) score of 1 or less; (2) adequate bone marrow reserve and organ function; and (3) no or stable brain metastases. This study was registered with ClinicalTrials.gov (NCT03917043). Recruitment is ongoing.

75% ORR in Patients with ALK+ NSCLC Previously Untreated with TKIs		
	ALK + NSCLC Patients Previously Untreated with TKIs (N = 16)	ALK + NSCLC patients with prior 2G TKI failure (N = 63)
ORR	12 (75%)	14 (22.2%)
mPFS, mo.	NE ¹	5.5
Intracranial ORR	2/2 (100%)	11/29 (37.9%)

Efficacy Results. Of patients with ALK-positive, TKI-naïve NSCLC (n = 14) treated at RP2D, the objective response rate (ORR) was 78.6% (11/14), and median progression-free survival (mPFS) was not reached. Of 22 patients with NSCLC resistant to second-generation ALK inhibitors (without ALK compound mutations or activation of bypass or downstream signaling pathways), 10 (45.5%) achieved partial response, with a mPFS of 13.6 months. Intracranial partial response occurred in 9/12 patients at the RP2D (intracranial ORR: 75.0%).

Safety Results. MTD was not reached, and RP2D was 1200 mg. The most common grade ≥3 treatment-emergent adverse events (TEAE) were anaemia [6 (4.2%)], alanine aminotransferase (ALT) increased [6 (4.2%)], electrocardiogram QT prolonged [5 (3.5%)], and pneumonia [5 (3.5%)]. The most common grade ≥3 treatment-related adverse events (TRAEs) were ALT increased [5 (3.5%)], QT prolonged [5 (3.5%)], and vomiting [2 (1.4%)]. There were no treatment-related deaths.

Development Highlights

- In April 2025, we released updated preclinical data of APG-2449 at AACR 2025, demonstrating enhanced antitumor activity with chemotherapy in preclinical models of small cell lung cancer, or SCLC, with activated FAK.
- In October 2025, we released clinical data from the phase 1 trial of APG-2449 in eClinicalMedicine. APG-2449 demonstrating favorable preliminary safety, pharmacokinetics, and efficacy in TKI-untreated or second-generation ALK-resistant NSCLC. Higher baseline tumor phosphorylated FAK levels were associated with greater APG-2449 treatment benefit. Targeting FAK signaling may provide a feasible strategy for overcoming second-generation ALK TKI resistance.

Alrizomadlin (APG-115)

Alrizomadlin is a novel, orally bioavailable, highly selective, small molecule inhibitor of mouse double minute 2 homolog, MDM2. Alrizomadlin is undergoing multiple clinical trials as a monotherapy or in combination with immunotherapy or chemotherapy in treating solid tumors and hematologic malignancies in sites around the world, including United States, China and Australia. We believe Alrizomadlin has potential to treat a number of serious rare and orphan diseases and address unmet medical needs in both adult and pediatric indications. Compared with adult tumors, pediatric solid tumors are characterized by low TP53 mutation frequency and high MDM2 amplification frequency. To date, the FDA has granted us six ODDs, including for soft-tissue sarcoma, gastric cancer and neuroblastoma, and two RPDD, including for neuroblastoma and retinoblastoma. In addition, we plan to pursue FTD, ODD and RPDD for our late-stage programs for Alrizomadlin in malignant peripheral nerve sheath tumors, or MPNST, and adenoid cystic carcinoma, or ACC, for which we reported preliminary Phase 2 results in 2022 and 2023, respectively. We are also developing Alrizomadlin for the treatment of other solid tumors and hematological malignancies, including AML, MDS, and T-PLL. Clinical trials evaluating Alrizomadlin are currently taking place in Australia, China and the United States. We plan to discuss with regulatory authorities and explore global registrational trials for Alrizomadlin for ACC or MPNST.

Malignant peripheral nerve sheath tumor (MPNST)

Malignant peripheral nerve sheath tumor, or MPNST, is an ultra-rare type of sarcoma that is very aggressive and has no available approved therapies. The causes of MPNST are not well understood, but it typically originates in the cells that cover and protect peripheral nerves and then grows quickly to invade other tissues. Chemotherapy and radiation have had limited effect on curbing the cancer, and efforts to develop targeted therapies that have shown success in other cancer, such as inhibitors of EGFR, mTOR and tyrosine kinase have not been successful to date. The current standard of care is aggressive surgical resection and, in some cases, amputation. However, surgery is sometimes not available due to size or location of the tumors, and traces of the cancer can remain and result in recurrence. MPNST remains plagued with high rates of recurrence and metastasis. The five-year survival rate is estimated to be 50% with median survival to be six years.

Adenoid cystic carcinoma (ACC)

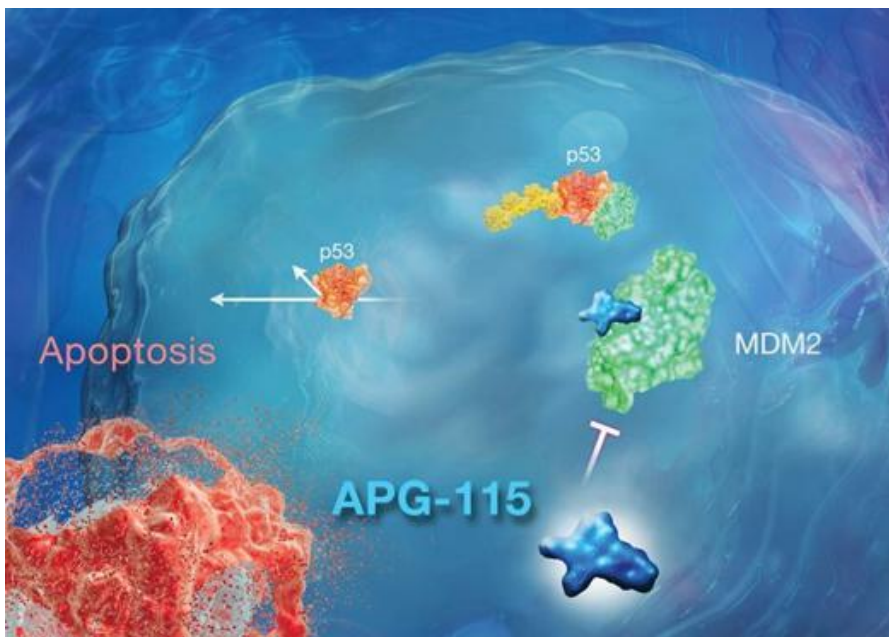
Adenoid cystic carcinoma, or ACC, is a rare form of malignant and persistent neoplasm that arises within secretory glands. It grows slowly along nerves continuing to recur years after diagnosis and treatment. Approximately four million people globally, and 1,300 in the United States, are diagnosed with ACC each year, with approximately 33 million people currently living with ACC, of which approximately 11,000 are in the United States. ACC is initially asymptomatic so it is often diagnosed late after the tumor is already at an advanced stage and has become metastatic. Currently, there are no NCCN standard treatment guidelines for managing all ACC. ACC patients are typically treated with surgery and radiation. Conventional chemotherapies are also used, but patients frequently develop resistance to such therapies, and clinical benefit has remained limited. ACC is characterized by frequent recurrences and metastases to sites such as the brain, lungs, liver, and bones. Most metastases develop 3 to 10 years after initial diagnosis, but can develop even later in life, so ACC patients require life-long monitoring.

Our Solution: Alrizomadlin

Alrizomadlin is a MDM2 inhibitor that has a stable chemical structure, high cell permeability, high binding affinity, and favorable PK profile. The MDM2 protein is an antagonist of the p53 transcription factor, a well-known tumor suppressor. Overexpression and amplification of MDM2 has been associated with various cancers, such as liposarcomas, soft tissue tumors, osteosarcomas, and esophageal carcinomas, and implicated in disease progression, treatment resistance and poor patient outcomes for other immunotherapies, such as PD-1/PD-L1 checkpoint inhibitors. Various approaches to inhibit MDM2 have been attempted for more than three decades, with hundreds of small molecule inhibitors evaluated in preclinical studies and clinical trials, but no MDM2 inhibitors have been approved to date.

Using a structure-based approach, we designed a new class of potent, selective, cell permeable, non-peptidic, small molecule inhibitors of the MDM2, and selected Alrizomadlin as our lead MDM2 inhibitor. Alrizomadlin has been generally well tolerated and has demonstrated clinical benefit in a number of indications, including in MPNST and ACC.

Mechanism of Action of Alrizomadlin (APG-115)



Select clinical trial results

Adenoid cystic carcinoma (ACC)

Phase 2 study of novel MDM2-p53 inhibitor Alrizomadlin (APG-115) with or without PD-1 mAb (toripalimab) in patients with ACC or other solid tumors

As of the data cutoff date of February 13, 2025, 57 patients with advanced ACC, malignant peripheral nerve sheath tumor (MPNST), liposarcoma (LPS), biliary-tract cancer (BTC), and other tumors were enrolled. Alrizomadlin monotherapy showed encouraging antitumor activity in patients with advanced ACC or MPNST. Alrizomadlin in combination with toripalimab was also well tolerated and demonstrated antitumor activity in patients with MPNST, BTC, and LPS.

Efficacy Results. In the monotherapy arm, 17 patients were efficacy-evaluable. The ORR was 16.7%, and the DCR was 100% in 12 patients with ACC. The DCR was 80% in 5 patients with MPNST, 4 of whom achieved stable disease (SD). In the combination arm, 29 patients were efficacy-evaluable. The ORR was 16.7% and the DCR was 100% in 6 patients with BTC. The ORR was also 16.7% and the DCR was 66.7% in 6 patients with LPS. Two patients with MPNST had confirmed partial response (PR) with prolonged progression free survival (PFS) of 60+ weeks and 96+ weeks, respectively. In 27 safety-evaluable patients treated with Alrizomadlin at the 150 mg dose level, 12 (44.4%) experienced grade 3 or higher TRAEs. Treatment-related SAEs were reported in 8 patients (29.6%). One patient discontinued treatment because of TRAE.

Safety Results. In the monotherapy arm, 24 patients were safety-evaluable, 33.3% reported grade 3 or higher treatment-related adverse events (TRAEs). Three patients (12.5%) experienced treatment-related serious adverse events (SAEs). One patient discontinued treatment because of TRAE. In the combination arm, 27 patients are safety-evaluable, patients treated with Alrizomadlin at the 150 mg dose level, 12 (44.4%) experienced grade 3 or higher TRAEs. Treatment-related SAEs were reported in 8 patients (29.6%). One patient discontinued treatment because of TRAE.

Other programs

We believe Alrizomadlin has the potential to treat a number of other solid tumors and hematological malignancies. In addition to the above-described trials. We are currently advancing the following clinical studies of Alrizomadlin in the United States and/or Australia:

- A Phase Ib/II study of Alrizomadlin monotherapy or in combination with pembrolizumab in patients with unresectable or metastatic melanoma (in collaboration with Merck & Co.) or other advanced solid tumors.
- A Phase IIa study evaluating the pharmacokinetics, safety and efficacy of Alrizomadlin as a single agent or in combination with Lisoftoclax in subjects with relapsed/refractory T-cell Prolymphocytic Leukemia, or R/R T-PLL, or NHL.
- A collaborative research study of Alrizomadlin monotherapy or in combination with chemotherapy in a Phase II study for the treatment of salivary gland cancer.

In addition, the CDE has granted approval for the following clinical trials of Alrizomadlin in China:

- A Phase Ib/II clinical study of Alrizomadlin in combination with anti-PD-1 antibody (JS001) toripalimab, for the treatment of patients with advanced liposarcoma (LPS) or other advanced solid tumors.
- A Phase Ib study of Alrizomadlin as a single agent or in combination with azacitidine or cytarabine in patients with R/R AML and relapsed/progressed high-/very high-risk MDS.
- A Phase I clinical study of Alrizomadlin alone or in combination with Lisoftoclax in children with solid tumors is ongoing, current data indicates that Alrizomadlin alone or in combination with Lisoftoclax showed a manageable safety profile, with preliminary antitumor activity in heavily pretreated relapsed/metastatic rhabdomyosarcoma (RMS) or other soft-tissue sarcomas (STSs).

Clinical Development Highlights

- In June 2025, we released clinical data from our Phase II study of Alrizomadlin as a single agent or in combination with PD-1 inhibitor toripalimab in patients with advanced adenoid cystic carcinoma, or ACC, or other solid tumors in a poster presentation at the 61st ASCO Annual Meeting. In the monotherapy arm, 17 patients were efficacy-evaluable. The ORR was 16.7%, and the DCR was 100% in 12 patients with ACC. The DCR was 80% in 5 patients with MPNST, 4 of whom achieved stable disease (SD). In the combination arm, 29 patients were efficacy-evaluable. The ORR was 16.7% and the DCR was 100% in 6 patients with BTC. The ORR was also 16.7% and the DCR was 66.7% in 6 patients with LPS.

Pelcitoclax (APG-1252)

Non-small cell lung cancer, or NSCLC, represents 80-85% of all lung cancers. A persistent cough is the most common symptom, making early detection of lung cancer difficult. The majority of lung cancer patients present with either stage 3 locally advanced or stage 3 metastatic disease. The current standard of care is chemotherapy or checkpoint inhibitors, but some patients who have specific mutations associated with NSCLC, such as an EGFR or ALK, have been responsive to targeted therapies targeting those mutations. For example, TKIs targeting EGFR mutants, or EGFR-TKIs, have been approved as frontline therapy for stage 3 or 4 NSCLC after chemotherapy. However, some patients have disease that remain resistant even to first-, second- and third-generation TKIs.

Our product candidate Pelcitoclax is a novel, highly potent, small molecule drug designed to restore apoptosis through dual inhibition of the Bcl-2 and Bcl-xL proteins. To date, the FDA has granted one ODD to Pelcitoclax for the treatment of SCLC.

In various clinical trials conducted in the United States, Australia and China, patients have been treated with Pelcitoclax as a monotherapy or in combination with other antitumor agents. Pelcitoclax has been well tolerated in patients to date using either weekly or biweekly intermittent dosing schedules. Preliminary antitumor activity was observed as a single agent in heavily pretreated patients.

Recent progress of Pelcitoclax is as follows:

Clinical progress

Pelcitoclax is currently under investigation in a variety of combination trials, including:

- A Phase Ib study of Pelcitoclax plus osimertinib in patients with epidermal growth factor receptor, or EGFR, mutant NSCLC in China;
- A Phase Ib/II study of Pelcitoclax as a single agent or in combination with other therapeutic agents in patients with R/R NHL in China.
- A Phase I study of Pelcitoclax in combination with cobimetinib in recurrent ovarian and endometrial cancers.

Plans for APG-1252

- Plan to initiate a Phase I study in China evaluating the safety and PK of APG-1252 as a monotherapy and in combination in R/R AML.
- Multiple IIT oncology studies to be conducted outside China.

In July 2021, we entered into a cooperative research and development agreement, or CRADA, with the National Cancer Institute, or NCI, of the National Institutes of Health, or NIH. Pursuant to the CRADA, the Division of Cancer Treatment and Diagnosis, or DTCD, agreed to sponsor Phase 1, 2 or 3 clinical trials to evaluate Pelcitoclax, alone or in combination with other compounds, for the treatment of cancer with our support and funding. We expect to collaborate on a series of clinical trials to evaluate the safety and efficacy of Pelcitoclax in solid tumors. The NCI may also conduct non-clinical correlative studies that focus on exploring the biologic activity of Pelcitoclax, as well as combination studies of the compound with other targeted agents. As data from the NCI- sponsored studies and our other trials emerge, we and the NCI will discuss additional studies to support the development of Pelcitoclax.

APG-3288

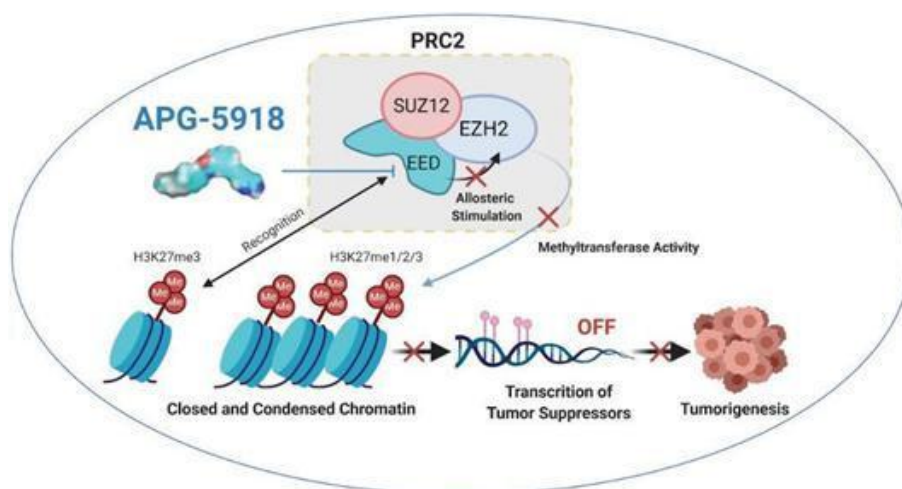
APG-3288 is our first disclosed novel, highly potent and selective BTK degrader developed utilizing Ascentage Pharma's proprietary proteolysis-targeting chimera (PROTAC) technology platform. Unlike conventional BTK inhibitors, APG-3288 is designed to act through degradation rather than inhibition, inducing rapid, potent, highly selective, and sustained degradation of both wild-type BTK and multiple BTK mutants associated with resistance to existing BTK inhibitors. Critically, this approach blocks the BCR-BTK signalling axis at its source, thereby overcoming resistance to BTK inhibitors and potentially providing a novel and differentiated therapeutic strategy for BTK-targeted treatment. In preclinical studies, compared to other BTK degraders in development, APG-3288 demonstrated more potent BTK degradation, higher selectivity, and more favorable PK properties that highlighted the drug's potential.

APG-3288 received IND clearance from the U.S. FDA in January 2026 and received IND application clearance from the China CDE in February 2026.

During 2026, we plan to conduct a global Phase I study evaluating APG-3288's PK, safety, tolerability, efficacy data in patients with relapsed/refractory B-cell malignancies, including in U.S. and China.

APG-5918

APG-5918 is a potent, orally bioavailable, and highly selective EED inhibitor. EED is a subunit of PRC2, which plays a role in regulating transcription of genes. It is believed that some mutations can activate PRC2 and result in silencing of key genes such as tumor suppressors and thereby allow the cancer to replicate more quickly. APG-5918 is believed to act upon EED and inhibit the PRC2's methyltransferase activity. We believe APG-5918 has demonstrated potential for treating patients with anemia, including beta-thalassemia and CKD-induced anemia.



Preliminary study results from our preclinical models of anemia were presented at the 2023 ASH Annual Meeting demonstrating APG-5918 has potential to improve CKD-induced hemoglobin, or Hb, insufficiency. This study investigates the effects of APG-5918 on Hb and fetal Hb, or HbF, *in vitro* in human CD34+ hematopoietic stem cells, or HSCs, from human cord blood and a CKD-induced anemia rodent model.

In the HSCs, the mRNA levels associated with Hb increased in a dose-dependent manner with treatment of APG-5918. Hb and HbF proteins were also dose-dependently upregulated. In the renal anemic rats, APG-5918 was administered orally and both body weight and hematologic parameters, such as levels of red blood cells and Hb, improved significantly in a dose-dependent manner compared to the control. Based on these results, we are currently evaluating APG-5918 in an NMPA-regulated, randomized, double-blind, placebo-controlled, Phase 1 single and multi- dose-escalation trial (NCT05773586) in anemic subjects. We believe this is the first clinical trial in China of an EED inhibitor amongst products with active trials.

We also initiated an FDA-regulated multi-center, open-label, Phase 1 trial (NCT05415098) of APG-5918 to evaluate the safety, pharmacokinetics and efficacy of APG-5918 in advanced solid tumors or lymphomas, including non-Hodgkin's lymphoma, that have progressed or are intolerant after treatment with approved therapies or for which there are no standard therapies available. The IND for this trial was submitted to the FDA on May 26, 2022. This clinical trial is currently taking place in China and the United States.

During 2026, we will advance the clinical development of APG-5918 in oncology and anemia in the U.S. and China.

Data Publication:

- In December 2025, we released the preclinical results on APG-5918 at ASH 2025, demonstrating that APG-5918 can overcome immunomodulatory drug (IMiD) resistance as a monotherapy as well as exhibiting synergistic antitumor activity when combined with IMiDs or cereblon E3 ligase modulators (CELMoDs) in preclinical MM models.
- In June 2025, we released preclinical results of APG-5918 at EHA 2025, demonstrating potent antitumor activity and synergistic activity with the histone deacetylase inhibitor tucidinostat in T-cell lymphoma (TCL) models.
- In April 2025, we released preclinical data on APG-5918 at AACR 2025, demonstrating that APG-5918 showed potent single-agent antitumor activity and enhanced efficacy in combination with enzalutamide in preclinical prostate cancer models.

APG-3288

APG-3288 is our first novel, highly potent and selective BTK degrader developed utilizing Ascentage Pharma's proprietary proteolysis-targeting chimera (PROTAC) technology platform. Unlike conventional BTK inhibitors, APG-3288 is designed to act through degradation rather than inhibition, inducing rapid, potent, highly selective, and sustained degradation of both wild-type BTK and multiple BTK mutants associated with resistance to existing BTK inhibitors. Critically, this approach blocks the BCR-BTK signalling axis at its source, thereby overcoming resistance to BTK inhibitors and potentially providing a novel and differentiated therapeutic strategy for BTK-targeted treatment. In preclinical studies, compared to other BTK degraders in development, APG-3288 demonstrated more potent BTK degradation, higher selectivity, and more favorable PK properties that highlighted the drug's potential.

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During 2026, we plan to conduct a global Phase I study evaluating APG-3288's PK, safety, tolerability, efficacy data in patients with relapsed/refractory B-cell malignancies, including in U.S. and China.

Discovery pipeline: protein degraders

Our deep understanding of heterobifunctional molecules and ligase biology has allowed us to develop protein degraders targeting traditionally undruggable proteins of interest implicated in key oncologic pathways. We believe we have the ability to develop differentiated protein degraders with improved PK/PD profiles resulting in less off-target effects than observed with degraders in clinical development by others. We also believe we can develop cancer therapeutics targeted at resistance mechanisms that have traditionally plagued small molecule inhibitors, with our protein degrader candidates.

In the first quarter of 2026, we announced that APG-3288, our first novel, highly potent and selective BTK degrader, received IND clearance from the FDA and CDE. In addition, we identified and nominated our targeted protein degrader, or TPD, candidate for pre-clinical development. This orally bioavailable degrader is targeting the p53-MDM2 pathway. In the last twenty years, many highly potent and orally active MDM2 inhibitors have been developed as a way to activate the p53 tumor suppressor gene, and several are currently in clinical development, including Alrizomadlin. However, inhibition of p53 often leads to upregulation of MDM2, which, in turn, has limited the efficacy of MDM2 inhibitors evaluated by others to date. Therefore, we believe that a degrader approach has the potential to be a transformative new strategy against these key oncology targets.

We have also identified several compounds from our protein degrader discovery capability that can rapidly reduce levels of the Bcl-xL protein in human cancer cell lines and thereby inhibiting their growth due to their dependency on Bcl-xL. Based on our initial studies, we believe our Bcl-xL protein degrader approach has the potential to demonstrate strong antitumor activity along with low levels of platelet toxicity. We are in the process of selecting and nominating our first Bcl-xL degrader candidate for pre-clinical development. The potential candidates exhibit high selectivity for the Bcl-xL target, demonstrating potent cellular and degradation activity, and showing remarkable in vivo efficacy in xenograft mice models.

Competition

The biotechnology and pharmaceutical industries, and the oncology drug sector specifically, are characterized by rapid change in current standard of care, evolving understanding of disease etiology, fierce competition and strong defense of intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

If any of our product candidates are approved for the indications for which we conduct clinical trials, they will compete with currently marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition, and availability of reimbursement.

With respect to products and product candidates targeting the BCR-ABL1 pathway, we are aware of companies that currently have products or are developing product candidates that can be competitive, including Novartis and Takeda, which are currently marketing asciminib and ponatinib, respectively.

With respect to product candidates targeting the Bcl-2 pathway, we are aware of companies that currently have products or are developing product candidates that can be competitive, including AbbVie, which is currently marketing venetoclax.

With respect to product candidates targeting the MDM2-p53 pathway, we are aware of companies that are currently developing product candidates that can be competitive, including Astex, Boehringer Ingelheim, and Kartos.

With respect to product candidates targeting the EED pathway, we are aware of companies that are currently developing product candidates that can be competitive, including Fulcrum and Oric.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical studies, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. In addition, our competitors' products may be more effective or more effectively marketed and sold than any treatment we or our development partners may commercialize and may render our product candidates obsolete or noncompetitive before we can recover the expenses related to developing and commercializing our product candidates.

License, collaboration and other agreements

We enter into collaborations with biotechnology, pharmaceutical companies and research institutes to advance the development and commercialization of our product candidates and to supplement our internal pipeline. We seek collaborations that will allow us to retain significant future participation in product sales through either profit-sharing or royalties paid on net sales. Below is an overview of some of our collaborations that have had a significant impact or that we expect may in the near term have a significant impact on our financial results. This is not a complete list, and we have several other collaborations or other agreements with third parties that could affect our results and financial condition.

Agreements with the University of Michigan

License agreement with the University of Michigan

In December 2010, and as amended May 2013, February 2016, May 2017, June 2017, August 2018, December 2018, January 2019, and November 2020, we entered into a license agreement with the Regents of the University of Michigan, or the Michigan Agreement and the University of Michigan respectively. Under the Michigan Agreement, the University of Michigan granted to us an exclusive, sublicensable (subject to certain restrictions) license under certain patent rights relating to Bcl-2 and/or Bcl-xL, IAP inhibitors and MDM2-p53 inhibitors, or the Patent Rights, to make, have made, import, use, market, offer for sale and sell products covered by the Patents Rights or manufactured using, or employed to practice, a Licensed Process, as defined further below, or the Licensed Products, and to practice processes or methods covered by the Patent Rights or using a Licensed Product, or the Licensed Processes in all the fields worldwide.

That Michigan Agreement was amended in August of 2025 by amending and restating the Michigan Agreement and entering into a new license agreement or the Michigan 2 Agreement. The amended and restated license agreement terms are substantially the same as the Michigan Agreement, except it does not apply to any new discoveries. The Michigan 2 Agreement terms are substantially the same as the amended and restated Michigan Agreement except that it applies to any new discoveries as well as adding annual payments and development and sales milestones.

We must (i) use commercially reasonable efforts to bring a full scope of Licensed Products to market or one or more Licensed Processes to commercial use through a program for exploiting the Patent Rights (including using commercially reasonable efforts to advance the clinical program to reach certain commercial, research and developmental milestones before certain dates), (ii) continue diligent marketing efforts throughout the life of the Michigan Agreement and (iii) do all that is necessary to obtain and retain any government approvals to manufacture and/or sell Licensed Products and/or use Licensed Processes for all of our relevant activities.

In connection with the entry into the Michigan Agreement, we paid the University of Michigan an upfront fee of US\$15 thousand, agreed to sponsor a research program for a certain period of time for no less than US\$600 thousand, and agreed to reimburse current and future patent expenses incurred by the University of Michigan. We have agreed to pay the University of Michigan a percentage of net sales of Licensed Products and uses or licenses of Licensed Processes as a royalty. This royalty ranges from the low to mid-single digits and is subject to certain reductions. In addition, we agreed to pay the University of Michigan a percentage of the revenue we receive from sublicensing Patent Rights (as defined therein) under the Michigan Agreement. We are required to pay the University of Michigan minimum annual royalties, which are creditable against the royalties owed for net sales of Licensed Products and uses or licenses of Licensed Processes and sublicense revenue. These minimum annual royalties vary by certain periods of time and range from amounts of US\$50 thousand up to US\$250 thousand. Our royalty obligations will expire on the date of the last to expire of the Patent Rights or until the Michigan Agreement is terminated. Upon the achievement of certain regulatory and commercial milestones, we are obligated to make milestone payments of up to US\$1.36 million in the aggregate.

Under the Michigan 2 Agreement, we paid the University of Michigan an upfront fee of US\$30 thousand and will pay an annual fee for 2025-2027 and another annual fee for 2028 to 2033. We have agreed to pay the University of Michigan the same percentage of net sales of Licensed Products and uses or licenses of Licensed Processes as a royalty. This royalty ranges from the low to mid-single digits and is subject to certain reductions. In addition, we agreed to pay the University of Michigan a declining percentage of the revenue we receive from sublicensing Patent Rights (as defined therein) under the Michigan Agreement. We are required to pay the University of Michigan minimum annual royalties, which are creditable against the royalties owed for net sales of Licensed Products and uses or licenses of Licensed Processes and sublicense revenue. These minimum annual royalties vary by certain periods of time and range from amounts of US\$50 thousand up to US\$250 thousand. Our royalty obligations will expire on the date of the last to expire of the Patent Rights or until the Michigan Agreement is terminated. Upon the achievement of certain development and commercial milestones, we are obligated to make milestone payments of up to US\$8.140 million in the aggregate.

Under the amended and restated Michigan Agreement and the Michigan 2 Agreement, the University of Michigan retains the right to control all filing, prosecution and maintenance of the Patent Rights, as well as interference and disputes (including litigation) regarding inventorship, but we agree to reimburse these costs. We have the right to direct and control the enforcement and defend the Patent Rights worldwide for or all fields but must notify the University of Michigan before filing any suit and adhere to the procedures set forth in both agreements. Both agreements will continue until the last to expire of the Patent Rights, unless terminated sooner in accordance with such agreements. Both agreements will terminate if we cease to carry on our business or if we fail to make payments to the University of Michigan, in each case upon written notice by the University of Michigan. The University of Michigan has the right to terminate both agreements upon any material breach or default by us upon written notice. We have the right to terminate both agreements upon written notice if we complete certain procedures described in those agreements, including suspending the manufacture, use and sale of the Licensed Products and Licensed Processes. After the licenses granted under the agreements terminate, if we have filed patent applications or obtained patents relating to any modification or improvement to the Licensed Products or the Licensed Processes within the scope of the Patent Rights, we agree upon request to enter into good faith negotiations with the University of Michigan for the purpose of granting licensing rights to such modifications or improvements in a timely fashion and under commercially reasonable terms.

BCL-2 license agreements

In December 2016, and as amended December 2016, we assumed from a third party, and entered into, a series of related agreements with the University of Michigan and/or Georgetown University, or collectively, the BCL-2 License Agreements. Among other agreements, we assumed, and entered into a certain (1) license agreement with the University of Michigan and Georgetown University, dated September 2003, and as amended June 2006, September 2006, November 2007, May 2010, July 2012 and August 2018, or the Michigan-Georgetown Agreement, and (2) amended and restated license agreement with the University of Michigan, dated August 2011, initially amended and restated June 2010, and as amended April 2012, November 2016 and August 2018, or the Michigan-Gossypol Agreement.

Under the Michigan-Georgetown Agreement, the University of Michigan and Georgetown University granted to us an exclusive, sublicensable (subject to certain restrictions) license under certain patent rights relating to Bcl-2 and/or Bcl-xL, or the Michigan/Georgetown Patent Rights) to make, have made, import, export, use, have used, market, offer for sale and sell products covered by the Michigan/Georgetown Patent Rights or manufactured using, or employed to practice, a Licensed Process, defined further below, or Michigan/Georgetown Licensed Products, and to practice processes or methods covered by the Michigan/Georgetown Patent Rights, or the Michigan/ Georgetown Licensed Processes, in the field of therapeutics for human use (and with respect to the Michigan/ Georgetown Licensed Products, also as a prognostic or diagnostic reagent, or the use in the development of the same solely for use in clinical trials sponsored by us to develop human therapeutics and not for sale to third parties), or the Michigan/Georgetown Field of Use, worldwide. Upon our written request, the University of Michigan will enter into good faith negotiations with us to expand the Michigan/Georgetown Field of Use to include veterinary uses and/or prognostic or diagnostic products (including reagents) for commercial purposes, and our right to request such negotiation will terminate with respect to prognostic and/or diagnostic products three years after notice is provided by either party to the other of an invention relating to such expanded use.

Under the Michigan-Gossypol Agreement, the University of Michigan granted to us an exclusive, sublicensable (subject to certain restrictions) license under certain patent rights relating to Gossypol co-crystals, or the Gossypol Patent Rights, to make, have made, import, export, use, have used, market, offer for sale and sell products covered by the Gossypol Patent Rights or manufactured, used, imported, offered for sale or sold using, or employed to practice, a Gossypol Licensed Process, as defined further below, or the Gossypol Licensed Products, and to practice processes or methods covered in whole or in part by the Gossypol Patent Rights, or the Gossypol Licensed Processes, for the treatment, palliation, prevention and diagnosis of all human and/or animal diseases, including the measurement, indication and/or prediction of the pharmacologic response to any of the foregoing, or the Gossypol Field of Use, worldwide. If the University of Michigan receives notice from a third party that such third party would like to negotiate for a license to any patent or patent application under the Gossypol Patent Rights for animal uses, or a Veterinary Use Sublicense, the University of Michigan will promptly notify us (date of such notification, the Notice Date) and request we enter into good faith negotiations with such third party for a Veterinary Use Sublicense. If the Gossypol Licensed Product identified as the subject of the Veterinary Use Sublicense, or the Sublicense Product, either would be directly competitive with any Gossypol Licensed Product (i) then sold or under actual development by us or (ii) scheduled to begin development or sublicensing by us within 24 months of the Notice Date, then we may decline the request for such sublicense and must notify the University of Michigan of our decision. Upon certain other prescribed conditions in such agreement, the University of Michigan may negotiate with the third party on our behalf to grant a Veterinary Use Sublicense.

Under the Michigan-Georgetown Agreement, we must (i) use commercially reasonable efforts to obtain and retain any governmental approvals to manufacture and/or sell the Michigan/Georgetown Licensed Products and/or use Michigan/Georgetown Licensed Processes for all of our relevant activities, (ii) use commercially reasonable efforts to bring one or more Michigan/Georgetown Licensed Products to market or one or more Michigan/ Georgetown Licensed Processes to commercial use through a program for exploiting the Michigan/Georgetown Patent Rights (including using commercially reasonable efforts to advance the clinical program to reach certain commercial, research and developmental milestones before certain dates), (iii) continue diligent marketing efforts for one or more Michigan/Georgetown Licensed Products or Michigan/Georgetown Licensed Processes throughout the life of the Michigan-Georgetown Agreement. Michigan/Georgetown Licensed Products used, leased or sold in the United States must be manufactured substantially in the United States unless a waiver is granted.

Under the Michigan-Gossypol Agreement, we must (i) use commercially reasonable efforts to obtain and retain any governmental approvals to manufacture and/or sell the Gossypol Licensed Products and/or use Gossypol Licensed Processes for all of our relevant activities, (ii) use commercially reasonable efforts to bring one or more Gossypol Licensed Products to market or one or more Gossypol Licensed Processes to commercial use through a program for exploiting the Gossypol Patent Rights (including using commercially reasonable efforts to advance the clinical program to reach certain commercial, research and developmental milestones before certain dates), (iii) continue diligent marketing efforts for one or more Gossypol Licensed Products or Gossypol Licensed Processes throughout the life of the Michigan-Gossypol Agreement. Gossypol Licensed Products used, leased or sold in the United States must be manufactured substantially in the United States unless a waiver is granted.

Under the Michigan-Georgetown Agreement, we agreed to pay the University of Michigan a percentage of net sales of Michigan/Georgetown Licensed Products and uses of Michigan/Georgetown Licensed Processes as a royalty. This royalty ranges from the low to mid- single digits and is subject to certain deductions. In addition, we agreed to pay the University of Michigan a percentage of the revenue we receive from sublicensing Michigan/Georgetown Patent Rights under the Michigan-Georgetown Agreement. We are required to pay the University of Michigan minimum annual royalties of US\$10,000, which are creditable against the royalties owed for net sales of Michigan/ Georgetown Licensed Products and uses of Michigan/Georgetown Licensed Processes. Our royalty obligations will expire on the date of the last to expire of the Michigan/Georgetown Patent Rights or until the Michigan- Georgetown Agreement is terminated. Upon the achievement of certain regulatory and commercial milestones, on a new chemical entity-by-new chemical entity basis for a certain therapeutic area, and for each new chemical entity in addition to that certain therapeutic area, we are obligated to make milestone payments of up to US\$1.15 million in the aggregate.

Under the Michigan-Gossypol Agreement, we agreed to pay the University of Michigan a percentage of net sales of Gossypol Licensed Products and uses of Gossypol Licensed Processes as a royalty. This royalty ranges from the low to mid-single digit and is subject to certain deductions. In addition, we agreed to pay the University of Michigan a percentage of the revenue we receive from sublicensing our Gossypol Patent Rights under the Michigan- Gossypol Agreement. We are required to pay the University of Michigan annual royalties of US\$2,500, which are creditable against the royalties owed for net sales of Gossypol Licensed Products and uses of Gossypol Licensed Processes. Our royalty obligations will expire on the date of the last to expire of the Gossypol Patent Rights or until the Michigan-Gossypol Agreement is terminated. Upon the achievement of certain regulatory and commercial milestones, on a new chemical entity-by-new chemical entity basis for a certain therapeutic area, and for each new chemical entity in addition to that certain therapeutic area, we are obligated to make milestone payments of up to US\$1.15 million in the aggregate.

Under the Michigan-Georgetown Agreement, the University of Michigan will retain the right to control all aspects of filing, prosecution and maintenance of the Michigan/Georgetown Patent Rights, but we agree to reimburse these costs (including for interference proceedings) and have a right to step in if the University of Michigan declines to perform such activities. We have the first option to enforce or defend the Michigan/Georgetown Patent Rights worldwide for the Michigan/Georgetown Field of Use but must notify the University of Michigan before filing any suit and adhere to the procedures set forth in the Michigan-Georgetown Agreement.

Under the Michigan-Gossypol Agreement, the parties agree to cooperate full to obtain, protect and defend patents arising out of the Gossypol Patent Rights, with the University of Michigan having the final say on any disputes (but we have a right to step in if the University of Michigan declines to perform these activities), and we agree to reimburse the costs related to the filing, prosecution, interference proceedings, and maintenance of the Gossypol Patent Rights. We have the first option to enforce or defend the Gossypol Patent Rights worldwide for the Gossypol Field of Use but must notify the University of Michigan before filing any suit and adhere to the procedures set forth in the Michigan-Gossypol Agreement.

The Michigan-Georgetown Agreement will continue until the last to expire of the Michigan/Georgetown Patent Rights, unless terminated sooner in accordance with such agreement. The Michigan-Georgetown Agreement will terminate if we cease to carry on our business or if we fail to make payments due to the University of Michigan, in each case upon written notice by the University of Michigan. Upon material breach, the University of Michigan has the right to terminate the rights granted with respect to the Michigan/Georgetown Licensed Product or Michigan/Georgetown Licensed Process at issue upon written notice. We have the right to terminate the Michigan- Georgetown Agreement upon written notice if we complete certain procedures described in the Michigan-Georgetown Agreement, including suspending our use of the Michigan/Georgetown Licensed Products and Michigan/Georgetown Licensed Processes. If the Michigan-Georgetown Agreement is terminated for reasons other than due to expiration of the term, if we have filed patent applications or obtained patents relating to any modification or improvement to the Michigan/Georgetown Licensed Products or the Michigan/Georgetown Licensed Processes within the scope of the Michigan/Georgetown Patent Rights, we agree upon request to consider entering into good faith negotiations with the University of Michigan or its future licensees for the purpose of granting licensing rights to such modifications or improvements in a timely fashion and under commercially reasonable terms.

The Michigan-Gossypol Agreement will continue until the last to expire of the Gossypol Patent Rights, unless terminated sooner in accordance with such agreement. The Michigan-Gossypol Agreement will terminate if we cease to carry on our business or if we fail to make certain payments or reports due to the University of Michigan, in each case upon written notice by the University of Michigan. Upon material breach, the University of Michigan has the right to terminate the rights granted with respect to the Gossypol Licensed Product or Gossypol Licensed Process at issue upon written notice. We have the right to terminate the Michigan-Gossypol Agreement upon written notice if we complete certain procedures described in the Michigan-Gossypol Agreement, including suspending our use of the Gossypol Licensed Products and Gossypol Licensed Processes. If the Michigan-Gossypol Agreement is terminated for reasons other than due to expiration of the term, if we have filed patent applications or obtained patents relating to any modification or improvement to the Gossypol Licensed Products or the Gossypol Licensed Processes within the scope of the Gossypol Patent Rights, we agree upon request to consider entering into good faith negotiations with the University of Michigan or its future licensees for the purpose of granting licensing rights to such modifications or improvements in a timely fashion and under commercially reasonable terms.

Strategic partnership with Innovent

In July 2021, we entered into a strategic partnership with Innovent pursuant to the HQP1351 Collaboration and License Agreement among Ascentage Pharma Group Corp Limited, Innovent and Guangzhou Healthquest Pharma Corp. Limited. Under the HQP1351 Collaboration and License Agreement, we granted Innovent development and commercialization rights for Olverembatinib and any finished form product comprising Olverembatinib, or the Licensed Products. Pursuant to the HQP1351 Collaboration and License Agreement, Innovent paid us an upfront payment of US\$30 million, and upon achievement of certain regulatory and commercial milestones Innovent is obligated to make milestone payments of up to an additional US\$115 million in the aggregate. We and Innovent have also agreed to use commercially reasonable efforts to carry out development and commercialization of the Licensed Products in the Field and for the Territory (as defined below).

We granted an exclusive (except as to us) license to Innovent to develop the Licensed Products and Olverembatinib for the treatment, palliation, diagnosis or prevention of human and veterinary oncology diseases, or the Field, in the PRC, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan (each a Region, or collectively, the Territory). We also granted an exclusive (except as to us) license to Innovent to commercialize the Licensed Products in Innovent's Covered Cities (as defined below).

We and Innovent agreed to use commercially reasonable efforts to commercialize any Licensed Products for Olverembatinib in the Territory after regulatory approval has been obtained. From the total potential market within the Territory, we and Innovent established the essential target market (the Essential Target Market). We are allocated 40% of the Essential Target Market, and Innovent is allocated 60%. From the Essential Target Market, we and Innovent each selected cities that we, respectively, will have the exclusive right to commercialize the Licensed Products in, or, in each case of our Company and Innovent, or the Covered Cities. For the five-year period after the first commercial sale of the first Licensed Product, we and Innovent, and respective affiliates, are prohibited from commercializing a certain Competing Product (as defined therein) in the Territory.

We retained the exclusive right, and are obligated, to supply Innovent the Licensed Products for use or sale in Innovent's Covered Cities and must use commercially reasonable efforts to fulfill this obligation.

The HQP1351 Collaboration and License Agreement will expire on a Licensed Product-by-Licensed Product and Region-by-Region basis between us and Innovent with respect to such Licensed Product in such country. The HQP1351 Collaboration and License Agreement may be terminated by either party in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances. In addition, on a Region-by-Region basis, the HQP1351 Collaboration and License Agreement may be terminated by Innovent or by us in the event a Licensed Product or another product containing the Licensed Molecule is withdrawn from the market by a regulatory authority in such Region, for such Region. Innovent may terminate the HQP1351 Collaboration and License Agreement at will upon specified written notice; provided, that in the event we are not able to commercialize the Licensed Products in Innovent's Covered Cities by a specified date, we have certain rights and obligations. In the event Innovent terminates the HQP1351 Collaboration and License Agreement for our uncured material breach or our specified bankruptcy, insolvency or similar circumstances, the commercialization license we granted to Innovent will become fully-paid, irrevocable and royalty-free.

Takeda exclusive option agreement

In June 2024, we entered into an exclusive option agreement with Takeda Pharmaceuticals International AG, or Takeda, and our affiliates, Guangzhou Healthquest Pharma Co., Ltd., and Ascentage Pharma (Suzhou) Co., Ltd., or the Takeda Exclusive Option Agreement, where we granted to Takeda an exclusive option to enter into an exclusive license agreement, under which Takeda would have the exclusive right (even as to us and our affiliates) to research, develop, import, export, make, have made, manufacture, have manufactured, use, commercialize, and otherwise exploit Olverembatinib, or the Compound, and any product comprising Olverembatinib, or the Product. The rights to be granted under the exclusive license agreement would be for any therapeutic, prophylactic, preventative or diagnostic use in or for animals and humans, or the Field, and would be granted worldwide, excluding the PRC, the Hong Kong Special Administrative Region, the Macau Special Administrative Region, Taiwan and the Russian Federation, or the Territory.

In connection with the Takeda Exclusive Option Agreement, we were paid US\$100.0 million by Takeda related to intellectual property income and option payment. In aggregate, under the Takeda Exclusive Option Agreement and the expected terms of the exclusive license agreement, we are eligible to be paid a one-time option exercise fee and certain development, commercial and sales milestone payments totaling up to approximately US\$1.2 billion and royalties in a range equal to 12-19% of net sales. In addition, in June 2024, we issued and sold to Takeda 24,307,322 ordinary shares, or the Takeda Shares, for an aggregate purchase price of US\$75 million. In connection therewith, we entered into a Registration Rights Agreement with Takeda, granting Takeda certain registration rights related to the filing of a resale registration statement covering the Takeda Shares, the filing of an unlimited number of shelf registration statements if the Company is qualified to make such filings, and granting of certain piggyback registration rights. Takeda's registration rights will terminate when Takeda no longer owns any Takeda Shares. A complete copy of the Registration Rights Agreement is filed as Exhibit 4.15 to this Annual Report on Form 20-F.

During the term of the Takeda Exclusive Option Agreement, we retain full control and decision-making authority, at our expense, over the development activities and strategy related to any Compound or Product worldwide, including the Territory, subject to certain obligations. Though we retain the sole right and responsibility, at our expense, to manufacture or have manufactured the Compound and the Product for the Field anywhere in the world, we also agreed to transition the technology to manufacture the Compound and Product to a third-party contract manufacturing organization, following which we will be eligible to receive a development milestone payment in the low double-digit millions.

Under the Takeda Exclusive Option Agreement, we agreed to use commercially reasonable efforts to develop and seek regulatory approval for a Compound and Product for a certain indication in the Territory. For the term of the Takeda Exclusive Option Agreement, we and our affiliates are prohibited from developing, manufacturing, commercializing or otherwise exploiting any Competing Product (as defined in the Takeda Exclusive Option Agreement), and we are obligated in certain situations to take certain actions related to our obligation to not develop, manufacture, commercialize or otherwise exploit any Competing Products.

As of the date of this Annual Report, Takeda has not exercised its option under the Takeda Exclusive Option Agreement, which will expire upon the earliest of: (x) the end of the option initiation period if no option initiation notice was timely provided; (y) the end of the option exercise period if no option exercise notice was timely provided; or (z) the effective date of the exclusive license agreement. If at the end of the option initiation period or option exercise period, Takeda has not timely provided an option initiation notice or option exercise notice, as applicable, due to government investigations under any antitrust or foreign direct investment laws, then the Takeda Exclusive Option Agreement will not automatically terminate, and Takeda will have the right to issue an option exercise notice at the closing of such investigations.

The Takeda Exclusive Option Agreement also may be terminated by Takeda or us in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances. In addition, the Takeda Exclusive Option Agreement may be terminated by Takeda or us in the event of an uncured material breach by the other party. In the event Takeda has the right to terminate the Takeda Exclusive Option Agreement for our uncured material breach or fraud, then Takeda may, in lieu of termination, have other rights. Takeda may terminate the Takeda Exclusive Option Agreement at any time in its sole discretion upon providing 30 days prior written notice.

Intellectual property

Intellectual property rights are fundamental to our business. Through our robust research and development, or R&D, platform and research collaborations, we have strategically developed a global intellectual property portfolio, which includes exclusive licenses to issued patents and patent applications worldwide with respect to Olverembatinib, Lisoftoclax and our other drug candidates. For Olverembatinib, Healthquest Pharma, our wholly owned subsidiary, acquired certain relevant patents from Guangzhou Institutes of Biomedicine and Health, Chinese Academy of Sciences or GIBH. Our comprehensive and growing intellectual property portfolio positions us to capture market potential globally.

The proprietary nature of, and protection for, our drug candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines. We have obtained or licensed patents relating to certain of our drug candidates and are pursuing additional patent protection for them and for our other drug candidates and technologies. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Moreover, trade secrets can be difficult to protect. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For more information on these and other risks related to intellectual property, see “Item 3. Key Information—D. Risk Factors—Risks related to our intellectual property.” Additionally, we have registered and unregistered trademarks, including amongst others, our Company name, as well as domain names incorporating some or all of these trademarks.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important products, technologies, inventions and know-how related to our business and our ability to defend and enforce our patents and other intellectual property, preserve the confidentiality of our trade secrets and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our development programs.

As of December 31, 2025, patent rights held by us relating to our drug candidates include the following:

With respect to Olverembatinib, our material patents consist of two issued U.S. patents, four issued PRC patents, one pending PRC patent application, and other international patents and patent applications directed to compositions of matter and processes of manufacturing, as well as one issued U.S. patent, five pending non-provisional U.S. patent applications, three PRC issued patents, two PRC patent applications, and other international patents and patent applications directed to methods of treatment, as well as one issued U.S. patent, one pending non-provisional U.S. patent application, one issued PRC patent, and other international patents and patent applications directed to pharmaceutical formulations, as well as one pending non-provisional U.S. patent application, one issued PRC patent application, and other international patents and patent applications directed to polymorphs of Olverembatinib. These patents and patent applications, if issued, are expected to expire between at least 2030 and 2045, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The following table summarizes our material patents with respect to Olverembatinib:

Olverembatinib			
Type of patent	Owned or licensed	Number of patents and non-provisional patent applications (in the U.S.)	Earliest possible expiration date of issued patents and pending patent applications, if issued (notwithstanding any patent term adjustment or patent term extension)
Composition of Matter	Owned	1	June 3, 2031
Methods of Treatment	Owned	6	April 26, 2044
Process	Owned	1	February 26, 2040
Formulation	Owned	1	December 9, 2039
Polymorph	Owned	1	July 1, 2041

With respect to Lisaftoclax, our material patents consist of eight pending non-provisional U.S. patent applications, eight issued U.S. patents, seven pending PRC patent applications, ten issued PRC patents, and other international patents and patent applications directed to methods of treatment or processes of manufacturing, as well as one pending non-provisional U.S. patent application, one issued U.S. patent, one issued PRC patent, and other international patents and patent applications directed to polymorphs of Lisaftoclax. We also have an exclusive license that covers three issued U.S. patents, two PRC issued patents, and other international patents and patent applications, directed to compositions of matter and methods of treatment.

These patents and patent applications, if issued, are expected to expire between at least 2037 and 2043, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The following table summarizes our material patents with respect to Lisaftoclax:

Lisaftoclax			
Type of patent	Owned or licensed	Number of patents and non-provisional patent applications (in the U.S.)	Earliest possible expiration date of issued patents and pending patent applications, if issued (notwithstanding any patent term adjustment or patent term extension)
Composition of Matter	Licensed	3	August 4, 2037
Method of Treatment	Owned	15	March 6, 2043
Process	Owned	1	July 1, 2041
Polymorph	Owned	2	March 5, 2041

With respect to Alrizomadlin, our material patents consist of five pending non-provisional U.S. patent applications, seven issued U.S. patents, one pending PRC patent application, eight issued PRC patents, and other international patents and patent applications directed to methods of treatment or processes of manufacturing, as well as one pending non-provisional U.S. patent application, one issued PRC patent and other international patents and patent applications directed to polymorphs of Alrizomadlin. We also have an exclusive license that covers one issued U.S. patent, one issued PRC patent, one pending PRC patent application, as well as other international patents and patent applications directed to compositions of matter.

These patents and patent applications, if issued, are expected to expire between at least 2035 and 2043, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The following table summarizes our material patents with respect to Alrizomadlin:

Alrizomadlin			
Type of patent	Owned or licensed	Number of patents and non-provisional patent applications (in the U.S.)	Earliest possible expiration date of issued patents and pending patent applications, if issued (notwithstanding any patent term adjustment or patent term extension)
Composition of Matter	Licensed	1	April 16, 2035
Method of Treatment	Owned	10	January 11, 2043
Process	Owned	1	July 10, 2040
Polymorph	Owned	1	January 22, 2041

With respect to Pelcitoclax, our material patents consist of two pending non-provisional U.S. patent applications, three issued U.S. patents, three pending PRC patent applications, four issued PRC patents and other international patents and patent applications directed to methods of treatment or processes of manufacturing, as well as one issued U.S. patent directed to polymorphs of Pelcitoclax. We also have an exclusive license that covers one issued U.S. patent, one issued PRC patent, as well as other international patents and patent applications directed to compositions of matter. These patents, and patent applications, if issued, are expected to expire between at least 2034 and 2041, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The following table summarizes our material patents with respect to Pelcitoclax:

Pelcitoclax			
Type of patent	Owned or licensed	Number of patents and non-provisional patent applications (in the U.S.)	Earliest possible expiration date of issued patents and pending patent applications, if issued (notwithstanding any patent term adjustment or patent term extension)
Composition of Matter	Licensed	2	January 15, 2034
Method of Treatment	Owned	4	April 1, 2041
Process	Owned	1	January 3, 2040
Polymorph	Owned	1	July 12, 2041

With respect to APG-5918, our material patents consist of one issued U.S. patent, one issued PRC patent, as well as other international patent applications directed to processes of manufacturing. We also have an exclusive license that covers one issued U.S. patent, one pending non-provisional U.S. patent application, one issued PRC patent, one PRC patent application, as well as other international patents and patent applications directed to compositions of matter, as well as two pending non-provisional U.S. patent applications, one PRC issued patent, one PRC patent application, and other international patents and patent applications directed to methods of treatment, as well as one pending non-provisional U.S. patent application, one PRC patent application, and other international patents and patent applications directed to pharmaceutical formulations, as well as one pending non-provisional U.S. patent application, one PRC patent application, and other international patents and patent applications directed to polymorphs of APG-5918. These patents and patent applications, if issued, are expected to expire between at least 2040 and 2044, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The following table summarizes our material patents with respect to APG-5918:

APG-5918			
Type of patent	Owned or licensed	Number of patents and non-provisional patent applications (in the U.S.)	Earliest possible expiration date of issued patents and pending patent applications, if issued (notwithstanding any patent term adjustment or patent term extension)
Composition of Matter	Licensed	1	July 16, 2040
Method of Treatment	Owned	2	August 12, 2042
Process	Owned	1	May 10, 2041
Formulation	Owned	1	June 6, 2044
Polymorph	Owned	1	January 29, 2043

With respect to APG-2449, our material patents consist of two pending non-provisional U.S. patent application, one issued U.S. patent, two pending PRC patent applications, three issued PRC patents, as well as other international patent applications directed to methods of treatment, as well as one issued PRC patent, one pending PRC patent application, and other international patents and patent applications directed to processes of manufacturing, as well as one pending non-provisional U.S. patent application, one pending PRC patent application, and other international patents and patent applications directed to polymorphs of APG-2449. We also have an exclusive license that covers two issued U.S. patent applications, two issued PRC patent, as well as other international patents and patent applications directed to compositions of matter. These patents and patent applications, if issued, are expected to expire between at least 2037 and 2044, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. The following table summarizes our material patents with respect to APG-2449:

APG-2449

Type of patent	Owned or licensed	Number of patents and non-provisional patent applications (in the U.S.)	Earliest possible expiration date of issued patents and pending patent applications, if issued (notwithstanding any patent term adjustment or patent term extension)
Composition of Matter	Licensed	2	August 28, 2037
Method of Treatment	Owned	3	March 22, 2044
Polymorph	Owned	1	July 25, 2044

With respect to other compounds, we have an exclusive license to other U.S. and PRC patents and patent applications, with issued and pending international counterparts which generally relate to our efforts to develop other small molecule drugs.

We cannot predict whether the patent applications we pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any proprietary protection from competitors. Even if our pending patent applications are granted as issued patents, those patents, as well as any patents we license from third parties, may be challenged, circumvented or invalidated by third parties.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the application. In certain jurisdictions extensions as compensation for regulatory delays are available. For example, in the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed co-owned patent. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. However, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. In certain foreign jurisdictions similar extensions as compensation for regulatory delays are also available. The actual protection afforded by a patent varies on a claim- by-claim and country-to-country basis for each applicable product and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, the patent positions of biotechnology and pharmaceutical products and processes like those we intend to develop and commercialize are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date. Changes in either the patent laws or interpretations of patent laws in the United States, the PRC and other countries may diminish our ability to protect our inventions, and enforce our intellectual property rights and more generally, could affect the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drug candidates and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own, or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of any such patent.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our consultants, scientific advisors and contractors and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drug candidates or processes, obtain licenses or cease certain activities. Our breach of any commercialize our drug candidates may have a material adverse impact on us.

In addition, substantial scientific and commercial research has been conducted for many years in the areas in which we have focused our development efforts, which has resulted in third parties having a number of issued patents and pending patent applications relating to such areas. Patent applications in the United States and elsewhere are generally published only after 18 months from the priority date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to drugs similar to our current product candidates and any future drug candidates, discoveries or technologies we might develop may have already been filed by others without our knowledge.

For more information on these and other risks related to intellectual property, see “*Item 3. Key Information—D. Risk Factors—Risks related to our intellectual property.*”

Commercialization

Ascentage Pharma entered an accelerated commercialization phase driven by a “dual-engine” strategy: the cornerstone product, Olverembatinib, achieved substantial growth following the implementation of NRDLs, while the newly launched product, Lisaftoclax, rapidly scaled following its initial launch during 2025. Throughout 2025, the Company rapidly expanded its commercial footprint, further strengthened its commercialization capabilities, and continued to grow its in-house sales team. At the same time, the Company remained focused on enhancing product competitiveness through clinical value and evidence-based data, laying a solid foundation for sustainable long-term growth.

on: Our in-house commercial team, which includes sales, marketing, market access, channel management, sales force effectiveness and sales training, includes more than 270 members, the vast majority of whom possess extensive professional experience in hematology-oncology field. For our two core products, the Company adopted a specialized, product-dedicated organizational structure. With the continued expansion of the commercial team and capabilities, we progressed from single-product commercialization to a “dual-engine” parallel strategy, supporting sustained growth of our cornerstone product, Olverembatinib, and the rapid uptake of the new launched product, Lisaftoclax. In 2025, our commercial team covered more than 1,500 hospitals and over 800 pharmacies for our two commercialized products. We also established strategic partnerships with leading pharmaceutical distributors, achieving national wide drug distribution coverage.

Manufacturing and facilities

We have established our own Suzhou facility as our global R&D center and manufacturing facility. The R&D center and the manufacturing facility were commissioned into use in the second half of 2021 and the fourth quarter of 2022, respectively. We refer to the global R&D center and manufacturing facility as the Suzhou Manufacturing Center.

The Suzhou Manufacturing Center has more than 200,000 square feet of space, and the manufacturing capacity for both oral solid tablet and capsule formulations is up to 250 million dosage units per year. We also maintain manufacturing capability at the Suzhou Manufacturing Center for injectable drug products, including lyophilized formulations. We have the necessary licenses and approvals to manufacture and supply Olverembatinib oral solid tablets for supply for global clinical trials as well as for commercial sales in the China market. We completed the drug tablet coating, debossing development, and the GMP production of Olverembatinib tablets, thereby preparing for future applications to the global regulatory authorities including the FDA.

Our Global Manufacturing Center and quality management system implemented at the site are compliant with the standards of the EU GMP, marking the achievement of a major milestone that will pave the way for our continued global expansion.

Our Global Manufacturing Center can produce and supply Lisoftoclax for our global clinical trials. In 2025, Lisoftoclax pre-approval inspections and GMP inspections for both drug substance and drug product were successfully completed through collaboration of Ascentage Pharma and contract development and manufacturing organizations, or CDMOs, which facilitated Lisoftoclax's NDA approval in China. After the NDA approval in July 2025, the first commercial batch of Lisoftoclax was successfully manufactured and launched to the market for the first prescriptions issued before the end of July 2025.

In addition, we lease a facility with a size of approximately 50,000 square feet for R&D and manufacturing in China Medical City, Taizhou, Jiangsu Province, China, where we produce and supply preclinical test articles and clinical trial materials for some of our drug candidates. We believe that the existing facilities are adequate for our current needs.

Employees and human capital

As of December 31, 2025, we had approximately 767 full-time employees, 447 of whom were engaged in research and development activities. None of our employees are represented by a labor union or covered under a collective bargaining agreement. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of share-based and cash-based compensation awards, in order to increase shareholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We are committed to supporting employee health and safety in the workplace through a generous health insurance program, as well as fostering an inclusive work environment that supports our workforce.

Legal proceedings

From time to time, we may be subject to various claims and legal actions that arise in the ordinary course of our business. As of the date of this Annual Report on Form 20-F, we are not a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, cash flows or financial condition. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Government regulation

U.S. regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products and medical devices. Generally, before a new drug, biologic or device can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. drug development

In the United States, the FDA regulates drugs under the FDCA and the Public Health Service Act. Drugs also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are considered small molecule drugs and must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practices, or GLPs;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an independent IRB, DSMBs, and/or ECs at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials as designed by the study protocol in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish substantial evidence of the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the filing for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical study and/or clinical trial sites that generated the data in support of the NDA filing;
- FDA review and approval of the NDA, potentially including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval commitments and requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

The data required to support an NDA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any current and future product candidates will be granted on a timely basis, or at all.

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals or models, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND application. An IND submission is a request for exemption from premarket approval requirements to enable the lawful shipment of the investigational product and to administer an investigational product to humans and must become effective before human clinical trials may begin. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND submission. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND submission is complete. An IND submission automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. IND sponsors follow a process similar to an IND submission, review and approval when filing a CTA with regulatory agencies in other countries.

Clinical trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians or academicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND submission. Furthermore, each clinical trial must be reviewed and approved by an IRB, DSMB, or EC for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must also approve the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND submission. If a foreign clinical trial is not conducted under an IND submission, the sponsor may submit data from the clinical trial to the FDA in support of an NDA. The FDA may accept an adequate well-controlled foreign clinical trial not conducted under an IND submission if the trial was conducted in accordance with the ethical principles contained in the Declaration of Helsinki pursuant to 21 CFR 312.120, incorporating the 1989 version of such declaration, or with the laws and regulations of the foreign regulatory authority where the trial was conducted, such as the European Medicines Agency, or EMA, whichever provides greater protection of the human subjects, and with GCP and GMP requirements, and the FDA is able to validate the data through an onsite inspection, if deemed necessary, and the practice of medicine in the foreign country is consistent with the United States.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap. Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug. Phase 2 clinical trials involve studies in disease-affected patients to determine the dose and dosing schedule required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted. Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA, or the sponsor may agree to a commitment to conduct such trials. Progress reports detailing the results of the clinical trials, among other information, must be submitted to the FDA at least annually. Sponsor is also responsible for submitting written IND safety reports, including reports of serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically significant increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials can potentially not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB, DSMB, or EC can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB, DSMB, or EC's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal safety studies and also must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process, as performed by the manufacturing facility, must be capable of consistently producing quality batches of our product candidates. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their labeled shelf life.

NDA review process

Following completion of the clinical trials, data is analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA is a request for approval to market the drug in the United States for one or more specified indications and must contain proof of safety and efficacy for a drug.

The application must include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be legally marketed in the United States.

Under the Prescription Drug User Fee Act of 1992, as amended, or PDUFA, each NDA must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each marketed human drug. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. In November 2023, the FDA issued a guidance on Real-Time Oncology Review, which allows applicants to provide the FDA with earlier access to critical efficacy and safety data, which can help streamline the review process and to potentially enable earlier FDA feedback to the applicant, including earlier feedback on data quality and potential review issues.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date of a new molecular-entity NDA, and six months from the filing date of a new molecular-entity NDA designated for priority review, to complete its initial review and respond to the applicant, commonly referred to as the ND's "PUDFA date". The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product 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. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult or controversial questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA, it will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The complete response letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application or request the opportunity for a hearing (although such hearings rarely have been granted by the FDA). Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Orphan drugs

Under the Orphan Drug Act of 1983, as amended, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, it discloses the identity of the therapeutic agent and its potential orphan use. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or in instances of drug supply issues. However, competitors may receive approval of either a different product for the same indication or the same product for a different indication, the latter of which could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if a product candidate is determined to be contained within the scope of the competitor's product for the same indication. In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), Congress, in an amendment to the Orphan Drug Act in the Consolidated Appropriations Act of 2026 or CAA, clarified that orphan drug exclusivity applies to the FDA's same approved use or indication within a rare disease, rather than the entire rare disease or condition. The change abrogated the decision in *Catalyst v. Becerra* and aligns the statutory text with the FDA's longstanding interpretation. This change makes explicit that orphan drug exclusivity blocks approval of the same drug only for the same approved use or indication, not for all uses within the broader designated disease. The amendment also applied retroactively. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union, or the EU, has similar, but not identical, requirements and benefits.

In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainty in the industry, and disrupt the FDA's normal operations.

Pediatric studies and exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act of 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Under the Best Pharmaceuticals for Children Act of 2002, pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. FDA may only grant pediatric exclusivity if existing patent or exclusivity protections for the drug would otherwise expire at least 9 months after the grant of the pediatric exclusivity; FDA has 180 days to make a pediatric exclusivity determination once the NDA sponsor submits study reports required under the written request.

Expedited review programs

The FDA has a fast-track program that is intended to expedite or facilitate the process of reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast-track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting with the FDA.

Any product submitted to the FDA for marketing, including under a fast-track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, such product must demonstrate 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, or IMM, which endpoint is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. The FDA may withdraw drug approval or require changes to the labeled indication of the drug if confirmatory post-market trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product. The Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Additionally, a drug may be eligible for designation as a breakthrough therapy if (a) the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and (b) preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast-track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast-track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-approval requirements and commitments

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse events and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, known as "off-label promotion," and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals, including the requirement for a REMS, to assure the safe use of the product. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for noncompliance with regulatory standards or if problems occur following initial marketing.

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 adverse events 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 the 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;
- suspension or revocation of product approvals;
- product seizure or detention;
- refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications 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, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

A therapeutic product may rely upon an in vitro companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. If an in vitro diagnostic is essential to the safe and effective use of the therapeutic product and if the manufacturer wishes to market or distribute such diagnostic for use as a companion diagnostic, then the FDA will require separate approval or clearance of the diagnostic as a companion diagnostic to the therapeutic product. According to FDA guidance, an unapproved or uncleared companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational medical device unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. The sponsor of the diagnostic device will be required to comply with the IDE regulations for clinical studies involving the investigational diagnostic device. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same clinical trial, if the trial meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the clinical trial protocol, the investigational product(s), and subjects involved, a sponsor may seek to submit an IDE alone (e.g., if the drug has already been approved by FDA and is used consistent with its approved labeling), or both an IND and an IDE.

At a high level, medical devices are classified by FDA into one of three classes based on their risk to users. A Class I device is considered low risk and is typically exempt from premarket review. A Class II device is considered moderate risk and is typically subject to premarket review in the form of the 510(k) notification and clearance process. A Class III medical device is considered high risk and is typically subject to premarket review in the form of the Premarket Approval or PMA process. Pursuing FDA approval/clearance of an in vitro companion diagnostic would require either a 510(k) PMA, or possibly a de novo classification for that diagnostic if there is not an applicable predicate device. The review of companion diagnostics involves coordination of review with the FDA's Center for Devices and Radiological Health. In June 2023, the FDA issued guidance on a voluntary pilot program on oncology drug products used with certain in vitro diagnostic tests, which is intended to provide greater transparency regarding the minimum performance characteristics necessary for certain oncology diagnostic tests. In April 2024, the FDA published a final rule regarding phasing out its enforcement discretion for most laboratory-developed tests and to amend the FDA's regulations to make explicit that in vitro diagnostics are medical devices under the FDCA, including when the manufacturer of the diagnostic product is a laboratory. These proposed changes and other regulatory changes pertaining to diagnostic products can increase the cost and time needed to develop new diagnostic tests and to bring them to the market.

510(k) clearance process

To obtain 510(k) clearance, a pre-market notification is submitted to the FDA demonstrating that the proposed device is substantially equivalent to a "predicate device," a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet required the submission of a PMA application. The FDA's 510(k) clearance process may take three to 12 months from the date the application is submitted and filed with the FDA but may take longer if the FDA requests additional information, among other reasons. In some cases, the FDA may require clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, which may significantly prolong the review process. Notwithstanding compliance with all these requirements, clearance is never assured. After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or require a PMA. In addition, the FDA may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, which may significantly affect the process.

De novo classification process

If a new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a different route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed. Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

PMA process

The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years or longer. The applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness, including information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for medical devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, which imposes extensive testing, control, documentation, and other quality assurance and GMP requirements.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, third-party payors, customers and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level), which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. In addition, once our product is approved in the U.S., we may be subject to transparency laws and patient privacy and security regulation by both the federal government and the states in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, or AKS, which prohibits, among other things, persons and entities, including a prescription drug or medical device manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or paying any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending or arranging for the prescription or purchase of any drug product may be subject to scrutiny if they do not qualify for an exception or safe harbor. Moreover, the Affordable Care Act, or the ACA, provides that the government may assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the civil False Claims Act of 1863, or FCA;
- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act (“FCA”) prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. This includes the civil FCA that can be enforced by private citizens through civil whistleblower or qui tam actions. Claims resulting from a violation of the federal AKS or the FDCA constitute a false or fraudulent claim for purposes of the FCA. Promotion that is deemed to be “off label” can also be the basis of FCA exposure. The DOJ can impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;
- Federal law includes provisions established under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and its implementing regulations addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs. Similar to the federal AKS, 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;
- HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys’ fees and costs;
- The federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services (“CMS”) information related to certain payments or other transfers of value made or distributed to physicians, certain non-physician practitioners and teaching hospitals, 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, state laws that require biotechnology companies to comply with the biotechnology industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their sales representatives, state laws that require biotechnology companies to report information on the pricing of certain drug products, and state and foreign laws that govern the privacy and security of health information in some circumstances (such as Washington’s My Health, My Data Act, which, among other things, provides for a private right of action), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 the Veterans Healthcare Act of 1992 which established the 340B program, and other rebates or discounts including those required or amended in the Medicare Modernization Act of 2003, the ACA and in the Inflation Reduction Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws. In addition, the distribution of pharmaceutical and/or medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, reporting, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical and/or medical device products. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act of 1970 as well as other applicable consumer safety requirements.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including 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, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

U.S. patent-term restoration and regulatory exclusivity

Patent term restoration can refer to two processes that may add time to the life of a patent for FDA-regulated products, a Patent Term Adjustment (PTA) and a Patent Term Extension (PTE). Both mechanisms potentially extend patent exclusivity. PTA is related to the patent prosecution while PTE is related to regulatory approval.

PTA provides for addition of time to the patent term based on delays by the patent office during the patent examination process. The length of the PTA is assigned by the patent office at the time of granting of the patent application. The patentee then may request reconsideration within two (2) months of the determination by the patent office and if the patentee does not agree with the determination they have 180 days to file suit in the Eastern District of Virginia for judicial review. In the future, we may seek reconsideration if a PTA if we disagree with a PTA determination made by the patent office.

PTE provides for an extension of a patent's term based on the time taken by FDA for regulatory review. Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for PTE. The Hatch-Waxman Act permits extension of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. PTE, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The PTE period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the PTE and the application for the PTE must be submitted prior to the expiration of the patent and within 60 days of FDA granting "permission to commercially market". The USPTO, in consultation with the FDA, reviews and approves the application for any PTE. In the future, we may apply for PTE for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain 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 accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval, which thus is termed "data" exclusivity because it proscribes the submission of an application based on other's data as opposed to the approval of an application. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement with respect to one or more patents listed for the drug in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) 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 which is termed "market" exclusivity because it proscribes the approval of an application which would lead to market entry as opposed to the submission of an application. This regulatory exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. 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 all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness or generate such data themselves.

U.S. coverage and reimbursement

Sales of our products will depend, in part, on the extent to which they are covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There is uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, government-sponsored plans, principal decisions about reimbursement for certain new products are typically made by CMS subject to coverage requirements for federal programs. CMS decides whether and to what extent, a new product will be covered and reimbursed under Medicaid, Medicare, and 340B, subject to applicable regulations and laws. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. Medicare Part B (physician-administered drugs) typically covers drugs deemed reasonable and medically necessary. Medicare Part D (self-administered drugs) includes requirements to cover certain therapeutic classes of drugs, including all or substantially all drugs in protected classes, which include oncology. Medicaid typically covers FDA-approved drugs where the manufacturer has a Medicaid agreement in place. However, plans and plan administrators may use other utilization management tools, including prior authorization, requirements to try another therapy first (step edits), or cost sharing. Commercial plans and providers have more flexibility, although may still be subject to minimum coverage requirements. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. In most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

U.S. healthcare reform

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price- controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the current U.S. administration is pursuing measures to reduce the cost of drugs in the United States, such as issuing two Executive Orders (EO) in 2025 directing federal agencies to take action to reduce the prices of drugs sold in the United States to match the lowest price available for the same drugs in comparably developed nations. It is currently unclear how, and to what extent, these measures may be implemented, and what impact their implementation would have on our Company.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Coverage requirements, required discounts, penalties, and pricing have later been amended under the ACA and the Inflation Reduction Act (IRA), passed in 2022. The IRA directs the federal government, through CMS, to select and set the prices of certain medicines approved by the FDA after 9 years (NDA) or 13 years (BLA), in both Part B and Part D. It also requires manufacturers of approved drugs to provide discounts on drugs through the Medicare Drug Rebate program in Part D and imposes penalties on manufacturers for price increases above a certain rate of inflation in Parts B and D. The IRA also limits patient out-of-pocket costs in total for certain covered drugs and specifically for certain drug types in Part D, including insulin and vaccines in both Parts B and D.

Under Part D, Medicare beneficiaries may enroll in private prescription drug plans that cover outpatient, or self-administered, prescription drugs that cover outpatient, or self-administered prescription drugs. Part D prescription drug plan sponsors can develop its own drug formulary that identifies which drugs it will cover, the level of cost sharing, and any utilization requirements, such as prior authorization. However, Part D prescription drug formularies must include drugs within each defined therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. There are six projected classes in Medicare Part D, 1) antidepressants; 2) antipsychotics; 3) anticonvulsants; 4) immunosuppressants for treatment of transplant rejection; 5) antiretrovirals; and 6) antineoplastics, where Part D plans are required to cover all or substantially all drugs, although the plans can require prior authorization or step therapy in certain circumstances. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Federal reimbursement and out-of-pocket limits in the Part D program may increase demand for products for which we receive marketing approval. However, negotiated prices for our products after rebates and discounts may be lower than the prices we might otherwise obtain; federal programs require additional rebates and discounts that are not required by commercial payers.

Drug coverage in Medicare Part B includes physician-administered drugs judged reasonable and medically necessary by CMS. Reimbursement is determined by a formula established by CMS, typically drawn from the drug's Average Sales Price reported by the manufacturer. As noted, the IRA also included certain reforms affecting Part B drugs and their cost-sharing. Drugs used incident to a hospital stay in Medicare are covered in Part A in typically through a bundled payment system established by CMS. Commercial insurance plans often follow CMS coverage.

Various industry stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government, asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The minimum Medicaid rebate, applied to drug sales in Medicaid Managed care and fee-for-service, on most branded prescription drugs of 23.1% of AMP with rebate calculation for "line extensions." Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts, calculated based on the AMP and Medicaid rebate amounts, to entities eligible to participate in the 340B drug pricing program.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 programs and reform government program reimbursement methodologies for drug products. The American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Programs rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have material impact on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization. These and other health reform measures that are implemented may have a material adverse effect on our operations. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could have a material and adverse effect on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services and medical products to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if approved, and our ability to achieve or maintain profitability.

Drug approval outside of the United States

In addition to regulations in the United States, we must obtain the requisite approvals from regulatory authorities in countries outside the U.S. prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside the U.S. have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require us to perform additional pre-clinical or clinical testing.

PRC regulation

In the PRC, we operate in an increasingly complex legal and regulatory environment. We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets forth a summary of the principal PRC laws, rules and regulations that we believe are relevant to our business and operations in China.

Introduction

China strictly supervises and regulates the development, approval, manufacturing and distribution of drugs. 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 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 CTA to conduct clinical trials in China and submit China clinical trial data, prior to applying 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 the Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices, or the Innovation Opinion, in October 2017. The expedited programs and other advantages under this and other recent reforms encourage drug manufacturers to seek marketing approval in China first, manufacture domestically, and develop drugs in high priority disease areas, such as oncology.

To implement the regulatory reform introduced by the Innovation Opinion, the National People’s Congress, or the NPC, and the National Medical Products Administration (formerly the China Food and Drug Administration, or the CFDA), or the NMPA, 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, or Drug Administration Law. The Drug Administration Law was promulgated by the SCNPC on September 20, 1984, and last amended on August 26, 2019 and took effect as of December 1, 2019. The Drug Administration Law is implemented by a high-level regulation issued by the State Council of the People’s Republic of China, or the State Council, referred to as the Implementing Regulations of the PRC Drug Administration Law. The NMPA has its own set of regulations further implementing Drug Administration Law; the primary one governing CTAs, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation, or DRR. The DRR was promulgated by the State Food and Drug Administration (the predecessor of CFDA and NMPA), or the SFDA, on February 28, 2005, and the latest amendment of DRR promulgated by SAMR, in January 2020 took effect as of July 1, 2020. PRC drug regulation is set to become increasingly stringent and standardized as the NMPA and other regulatory authorities issue more and more circulars and regulations to implement reforms.

Principal regulatory authorities

In the PRC, the principal regulatory authorities for drugs are the NMPA, the National Health Commission (formerly known as the National Health and Family Planning Commission), or the NHC, and the National Healthcare Security Administration, or the NHSA. The NMPA is the department in charge of the pharmaceutical industry of China. It is responsible for drafting 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 implementation. The Center for Drug Evaluation, or the CDE, 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 NHC is the 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 systems, organizing the formulation of national drug policies and national essential medicine systems, launching early warning mechanisms for the monitoring of the use and clinical comprehensive evaluation of medicines, as well as drug shortages, providing suggestions on the pricing policy of national essential medicines and regulating the operation of medical institutions and practicing of medical personnel.

The NHSA, a new authority established in May 2018, directly reports to the State Council and is responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance, and medical assistance, supervising and administering the healthcare security funds, formulating a uniform medical insurance catalog and payment standards on drugs, medical disposables, and healthcare services and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

Non-clinical research and animal experiment

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. Pursuant to the DRR, nonclinical safety evaluation study for drugs must be carried out by organizations with quality management standard certification for non-clinical safety evaluation study for drugs and must comply with the quality management standard for non-clinical safety evaluation study for drugs. On August 6, 2003, the SFDA (the predecessor of CFDA and NMPA) promulgated the Administrative Measures for Good Laboratories Practice for Non-clinical Drug Research, which was revised on July 27, 2017, 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 the SFDA on April 16, 2007 and amended on January 19, 2023 by the NMPA, which became effective on July 1, 2023, the 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. The 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 the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website.

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission on November 14, 1988 and amended on January 8, 2011, July 18, 2013 and March 1, 2017, respectively, by the State Council, the Administrative Measures on Good Practice of Experimental Animals jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001, using and breeding experimental animals is subject to rules and performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

Registration categories

Prior to engaging with the NMPA on research and development and approval, an applicant must determine the registration category for its product candidate (with such determination to be confirmed with the NMPA), which will determine the application requirements for its clinical trial and marketing application. Drug marketing registration applications are subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of chemical drugs is categorized by innovative chemical drugs, improved new chemical drugs, generic chemical drugs and others, and the registration applications of biological products is categorized by innovative biological products, improved new biological products and biological products on the market (including biological similar drugs) and others.

The Registration Category of Biological Products and the Data Requirements for Declaration, issued by NMPA on June 29, 2020 and became effective on July 1, 2020, replaced the former category of therapeutic biological products and stipulated that the therapeutic biological products should be classified into three categories: Category I refers to therapeutic biological products that have not been marketed anywhere in the world; Category II refers to improved new therapeutic biological products; and Category III refers to therapeutic biological products that have been marketed in China or abroad.

Expedited programs

The NMPA and its predecessors 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 CDE. The Announcement of Three Documents Including "Working Procedures for Review of Breakthrough Therapeutics Drugs (Interim)" promulgated by the NMPA on July 7, 2020 clarifies that during clinical trials of drugs, innovative drugs or improved new drugs that are used to prevent and treat severely life threatening diseases for which there are no available effective prevention and treatment methods or there is sufficient evidence to show such drugs have obvious clinical advantages compared with existing treatment methods, etc., applicants can apply for breakthrough therapeutic drug program in Phase 1 and Phase 2 clinical trials, usually no later than the start of Phase 3 clinical trials.

If admitted to one of these expedited programs, an applicant will be entitled to more frequent and timely communication with reviewers at the CDE, expedited review and approval and more agency resources throughout the review approval process.

The NMPA also permits conditional approval of certain medicines based on early phase China clinical trial data or 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 for drugs that treat orphan indications. In 2018, NMPA and NHC established a conditional approval program for drugs designated by the CDE that have been approved in the United States, European Union and Japan within the last 10 years.

Clinical trials and marketing approval

Upon completion of preclinical studies, a sponsor typically needs to conduct clinical trials in China for registering a new drug. The materials required for this application and the data requirements are determined by the registration category. The NMPA has taken several steps to increase efficiency for approving CTAs, and it has also significantly increased monitoring and enforcement of the Administrative Regulations of Quality of Drug Clinical Practice, or the PRC's GCP, to ensure data integrity. The PRC's GCP was initially promulgated by the SFDA on August 6, 2003, and the latest version came into force on July 1, 2020.

Trial approval

The clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions. In October 2014, the CFDA, the NHC and the National Administration for Chinese Medicine issued an Administration Rule for the Project of Clinical Trial Conducted by Medical and Healthcare Institution, pursuant to which, clinical trials conducted by medical and healthcare institutions may only be conducted in projects approved by such medical and healthcare institution, and after the approval of such clinical trial project, such medical and healthcare institution must file such approval with the medical and healthcare authority that issues its operating license for records.

On January 30, 2015, the CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), or the Multi-Center Clinical Trial Guidelines, which took effect as of March 1, 2015, aiming to provide guidance for the regulation of application, implementation, and administration of international multi-center clinical trials, or IMCCT, in China. Pursuant to such guidelines, IMCCT applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Applicants may make use of the data derived from the international multi-center clinical trials for application to CFDA for approval of an NDA after satisfying certain requirements under the Guidelines.

On October 10, 2017, the CFDA promulgated the Decision on Adjusting Items concerning the Administration of Imported Drug Registration, pursuant to which, if the IMCCT of a drug is conducted in China, the IMCCT drug does not need to be approved or entered into either a Phase II or III clinical trial in a foreign country, except for vaccines, and the application for drug marketing authorization can be submitted directly after the completion of the IMCCT. With respect to applications for imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required.

Drug clinical trial registration

In 2015, the CFDA began to issue an umbrella approval for all phases (typically three) of a new drug clinical trial, instead of issuing approval phase by phase. For certain types of new drug candidates, CTAs may be prioritized over other applications and put in a separate expedited queue for approval. The NMPA has now adopted a system for clinical trials of new drugs where trials can proceed if, after 60 business days, the applicant has not received any objections from the CDE. China is also expanding the number of trial sites by changing from a clinical trial site certification procedure into a notification procedure. According to the DRR, after the completion of the pharmaceutical, pharmacological, and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical, and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and, if no notice of decision is issued within the time limit, the application of clinical trial shall be deemed as approval. In addition, the applicant must, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trial Information Platform. During the drug clinical trials, the applicant must update registration information continuously and register information of the outcome of the drug clinical trial upon completion. The applicant is responsible for the authenticity of the drug clinical trial information published on the platform. On September 6, 2013, the CFDA released the Announcement on Drug Clinical Trial Information Platform, pursuant to which, applicants must complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and must complete registration of certain follow-up information before the first subject's enrollment in the trial. If approval of the foregoing pre-registration and registration is not obtained within one year after obtaining the clinical trial approval, the applicant must submit an explanation, and if the procedure is not completed within three years, the clinical trial approval will be automatically be annulled.

Human genetic resources approval

On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that non-PRC-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC. The State Council issued the Regulations on the Administration of Human Genetic Resources, or the HGR Regulation, which became effective on July 1, 2019 and was amended on May 1, 2024. The HGR Regulation regulates the collection, preservation, usage and external provision of China's human genetic resources. According to this regulation, "human genetic resource" includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Ministry of Science and Technology is responsible for the management of human genetic resources at the national level, and the administrative departments of science and technology under the provincial governments are responsible for the management of human genetic resources at local level. Non-PRC entities, non-PRC individuals and such entities established or actually controlled thereby are not allowed to collect or preserve China's human genetic resources (including organs, tissues, cells and other genetic materials of human genome and gene) or provide human genetic resources abroad, while they are prohibited from using China's human genetic resources unless they have obtained an approval from relevant PRC government authority or have filed with relevant government authority for international cooperation with a Chinese entity. The HGR Regulation formalized the approval requirements pertinent to research collaborations between Chinese and non-PRC-owned entities. Pursuant to the new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China. On May 26, 2023, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources, effective from July 1, 2023, which further provided specific provisions on the collection, preservation, utilization and external provision of human genetic resources of the PRC.

Trial exemptions and acceptance of non-PRC data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, or the Guidance Principles, as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of non-PRC clinical trials must meet the authenticity, completeness, accuracy and traceability requirements and such data must be obtained consistent with the relevant requirements under the PRC's GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH. Sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without the need for pre-approval clinical trials inside China. Specifically, on October 23, 2018, the NMPA and the NHIC issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, which established a program permitting drugs that have been approved within the last ten years in the United States, European Union or Japan and that (1) treat orphan diseases, (2) prevent or treat serious life-threatening illnesses for which there is either no effective therapy or prevention in China, or (3) prevent or treat serious life-threatening illnesses and the non-PRC-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug is marketed.

Clinical trial process and good clinical practices

Pursuant to the DRR, a clinical trial consists of Phases I, II, III and IV as well as a bioequivalence trial. Based on the characteristics of drugs and the research objective, the research contents must include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval and comply with the PRC's GCP. The NMPA conducts inspections to assess the PRC's GCP compliance and will cancel the CTA if it finds substantial issues.

To improve the quality of clinical trials, the CFDA promulgated the PRC's GCP on August 6, 2003, which was further amended on April 23, 2020 and came into effect on July 1, 2020. To ensure the quality of clinical trials and the safety of human subjects, the PRC's GCP provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the PRC's GCP enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials. The PRC's GCP stipulated that the sponsor will bear the expenses for medical treatment and the corresponding compensation for any human subject who is harmed or dies due to reasons connected with the clinical trial. The sponsor and investigator will pay the human subject the compensation or indemnification in a timely manner. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials will be subject to record-filing administration. The conduct of clinical trials must adhere to the PRC's GCP, and the protocols must be approved by the ethics committees of each study site. Pursuant to the newly amended Drug Administration Law, and the Regulations on the Administration of Drug Clinical Trial Institution jointly promulgated by NMPA and NHC on November 29, 2019, and effective from December 1, 2019, drug clinical trial institutions must be under filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs do not need to be filed.

New drug application and approval

Upon completion of clinical trials, a sponsor may submit clinical trial data to support marketing approval for the drug. For imported drugs, this means issuance of an imported drug license. For NDAs in China, sponsors must submit data derived from domestically manufactured drugs in support of a drug approval. Under the current regime, upon approval of the registration application, the NMPA will first issue a new drug certificate to the applicant. Only when the applicant is equipped with relevant manufacturing capability will the NMPA issue a Drug Approval Serial Number, which is effectively the marketing approval allowing the holder to market/ commercialize the drug in China.

Pursuant to the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated on August 9, 2015, the State Council published the policy for carrying out a pilot plan for the drug marketing authorization holder mechanism.

Pursuant to the newly amended Drug Administration Law, under the drug marketing authorization holder mechanism, an enterprise or a research and development institution which has obtained a drug registration certificate is eligible to be a pharmaceutical marketing authorization holder, and this pharmaceutical marketing authorization holder shall be responsible for nonclinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The pharmaceutical marketing authorization holder may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and may engage pharmaceutical distribution enterprises with drug distribution license for the distribution activities. Upon the approval of the medical products administrative department under the State Council, a drug marketing authorization holder may transfer the drug marketing license and the transferee will have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness, and quality controllability of drugs, and fulfill the obligations of the drug marketing license holder.

Manufacturing and distribution

According to the newly amended Drug Administration Law and the implementing measures of the Drug Administration Law, all facilities that manufacture drugs in China must receive a Drug Manufacturing License with an appropriate “scope of manufacturing” from the local drug regulatory authority. This license must be renewed every five years. Similarly, to conduct sales, importation, shipping and storage, or distribution activities, a company must obtain a Drug Distribution License with an appropriate “scope of distribution” from the local drug regulatory authority, subject to renewal every five years.

China has formed a “Two Invoice System” to control distribution of drugs. The “Two-Invoice System” generally requires that no more than two invoices may be issued throughout the distribution chain, with one from the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to their exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary (or between the wholly owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. Compliance with the Two-Invoice System will become a prerequisite for pharmaceutical companies to participate in procurement processes with public hospitals, which currently provide most of China’s healthcare. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process for centralized purchasing, a process used by the NHSA to negotiate the prices of drugs and medical devices with manufacturers, aiming to reduce costs and ensure consistent access to essential healthcare products across the country. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

The Two-Invoice System was first implemented in 11 provinces that are involved in pilot comprehensive medical reforms, but the program has expanded to nearly all provinces, which have their own individual rules for the program.

Advertising and promotion of pharmaceutical products

China has a strict regime for the advertising of approved drugs. No unapproved drugs may be advertised. The definition of an advertisement is very broad, and it can be any media that directly or indirectly introduces the product to end users. There is no clear line between advertising and any other type of promotion.

Each advertisement for drugs requires an approval from a local drug regulatory authority, and the content of an approved advertisement may not be altered without filing a new application for approval. An enterprise seeking to advertise a prescription drug may do so only in medical journals jointly designated by NMPA and the NHC, and the advertisement for a prescription drug shall tag “this advertisement is for medical and pharmaceutical professionals reading only.” Drug advertisements are subject to strict content restrictions, which prohibit recommendations by doctors and hospitals and guarantees of effectiveness. Advertising that includes content that is outside of the drug’s approval documentation, off-label content, is prohibited. False advertising can result in civil suits from end users and administrative liability, including fines. In addition to advertisements, non-promotional websites that convey information about a drug must go through a separate approval process by a local drug regulatory authority.

Post-marketing surveillance

Pursuant to the amended Drug Administration Law, the drug marketing authorization holder is responsible for the monitoring, reporting and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of Drug Administration Law. Marketing authorization holders, pharmaceutical manufacturer, pharmaceutical distributors, and medical institutions will regularly inspect the quality, efficacy and adverse reactions of drugs manufactured, distributed and used by them. Cases of suspected adverse reactions will be promptly reported to the drug administrative authorities and the competent health administrative authority. The drug marketing authorization holder will stop selling, notify the relevant pharmaceutical distributors and medical institutions to stop sales and use, recall sold drugs, promptly announce recall information if the drugs have quality issues or other safety hazards.

National reimbursement drug list

On March 3, 2015, the General Office of the State Council issued the Outline for the Planning of the National Medical and Health Service System (2015-2020), which aimed to establish a basic medical and healthcare system that covers both rural and urban citizens by 2020. Participants of the national medical insurance program and their employers, if any, are required to contribute to the insurance program monthly. Program participants are eligible for full or partial reimbursement of the costs of medicines included in the National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL.

The NHSA, the Ministry of Human Resources and Social Security, together with other government authorities, have the power to determine which medicines are listed in the NRDL. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs. Patients purchasing medicines included in List A will be reimbursed the purchase price through the basic medical insurance program in full. List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs. Patients purchasing medicines included in List B are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price through the basic medical insurance program.

The NRDL is always linked to centralized purchasing, and is regularly updated to include new drugs, adjust the reimbursement status of existing drugs, or remove some drugs that are no longer eligible. On December 7, 2023, the NHSA and the Ministry of Human Resources and Social Security released the 2023 NRDL, the scope of which was expanded to cover 3,088 drugs in total.

Other significant PRC regulations affecting our business activities in the PRC

PRC regulations of foreign investment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC, or the PRC Company Law, which was adopted by the SCNPC in December 1993, implemented in July 1994, and subsequently amended in December 1999, August 2004, October 2005, December 2013 and October 2018. Under the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies. Pursuant to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail. The most recent amendment of the PRC Company Law was adopted in December 2023 and came into effect on July 1, 2024, which introduced multiple updates to the current PRC Company Law with regard to, among others, the capital contribution liability, corporate governance structure and responsibilities of directors, supervisors, senior managers, controlling shareholders and actual controllers.

Investment activities in China by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the latest Special Administrative Measures (Negative List) for Foreign Investment Access (2021), or the Negative List, which was promulgated by the Ministry of Commerce of the PRC, or MOFCOM, and the National Development and Reform Commission on December 27, 2021 and took effect on January 1, 2022. The Negative List sets out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List are administered under the principle of equal treatment to domestic and foreign investment.

On March 15, 2019, the NPC promulgated the Foreign Investment Law of the PRC, or FIL, which became effective on January 1, 2020 and replaced Foreign Investment Enterprise Law of the PRC (1986) (as amended in 2000 and 2016). Pursuant to FIL, the foreign-invested enterprises are entitled to pre-establishment national treatment and must comply with the special entry administrative measures (as provided in a negative list). FIL provides the free inward and outward transfer of the contributions, profits, capital gains, etc. of the foreign investor within the territory of the PRC in RMB or a foreign currency in accordance with the law and a foreign investment information reporting system and emphasizes the protection of the intellectual property rights of foreign investors and foreign-invested enterprises.

On December 30, 2019, for the purpose of further promoting the foreign investment administration and simplifying the administrative procedures, the MOFCOM and the SAMR promulgated the Measures on Reporting of Foreign Investment Information, which became effective on January 1, 2020, and suspended the Interim Measures for Record-filing Administration of the Incorporation and Change of Foreign-invested Enterprises on the same date. Under this regulation, an information reporting system applies to foreign investors' mergers and acquisitions of domestic non-foreign-invested enterprises and strategic investments in listed companies, provided that they comply with the implementation of special access administrative measures prescribed by the PRC regulators and do not involve the mergers and acquisitions of affiliates. Specifically, under the information reporting system, where a new foreign-invested enterprise is incorporated or a non-foreign invested enterprise changes to a foreign-invested enterprise through acquisition, merger or other means, such incorporation or change no longer requires approval or record-filing of MOFCOM, but shall be reported online to the commerce administrative authorities through the Enterprise Registration System and the National Enterprise Credit Information Publicity System, together with the registration with the relevant department of the SAMR through the same systems.

PRC regulations of environment protection

We are subject to Chinese environmental protection laws and regulations promulgated by state and local governments concerning environmental protection regarding construction projects, the use, discharge and disposal of toxic and hazardous materials, and the discharge and disposal of wastewater, solid waste and waste gases and industrial noise.

Pursuant to the Environmental Protection Law of the PRC, or the Environmental Protection Law, which was promulgated by the SCNPC on and became effective as of December 26, 1989, and amended on April 24, 2014 and came into force on January 1, 2015, all enterprises and institutions which discharge pollutants must adopt measures to prevent and control pollution and damage to the environment from waste gas, waste water, waste residues, medical waste, dust, malodorous gases, radioactive substances, noise, vibration, ray radiation and electromagnetic radiation generated in the course of production, construction or other activities. The relevant authorities are authorized to impose various types of penalties on the persons or entities in violation of the environmental regulations, including fines, restriction or suspension of operation, shut-down, detention of office- in-charge, etc.

China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

Patents

Pursuant to the PRC Patent Law, most recently amended in December 2008, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten years from the date of application. The PRC Patent Law adopts the principle of “first-to-file” system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the China National Intellectual Property Administration, or CNIPA. Normally, the CNIPA publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the CNIPA for a substantive examination within three years from the date of application.

Article 19 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the CNIPA for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. The PRC Patent Law also sets up the framework and adds the provisions for patent linkage and patent term extension.

Patent enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offences such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner’s patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner’s or an interested party’s request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the calculation standards referenced above. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

The most recent amendment to the PRC Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, describes the general principles of linking generic drug applications to pharmaceutical patent protection, also known as Patent Linkage. In July 2021, the NMPA and the CNIPA jointly published the Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) providing an operating mechanism for Patent Linkage. Upon notification of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after CDE publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. For chemical drugs, the NMPA would initiate a nine-month approval stay period upon notification. If the patentee or the interested person cannot secure a favorable court judgment or a decision from the CNIPA within the nine-month period, the NMPA can grant marketing authorization to the generic applicant after the nine-month period expires.

Trade secrets

According to the PRC Anti-Unfair Competition Law promulgated by the SCNPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019, or, collectively, the PRC Anti-Unfair Competition Law, the term “trade secrets” refers to technical and business information that is unknown to the public that has utility and 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 contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder’s requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of such illegal conduct but nevertheless obtains, uses or discloses trade secrets of others trade secrets, the third party may be deemed to have committed a misappropriation of the others’ trade secrets.

Trademarks and domain names

According to the Trademark Law of the PRC, promulgated by the SCNPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its implementation rules, or, collectively, the Trademark Law, the Trademark Office of the National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout China. The Trademark Law has adopted a “first-to-file” principle with respect to trademark registration.

Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology in August 2017 and effective November 2017. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of Chinese internet domain names.

PRC regulations on labor contracts and social security

The Labor Law of the PRC, which was promulgated by the SCNPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009 and December 29, 2018, the Labor Contract Law of the PRC that became effective on January 1, 2008, as amended on December 28, 2012, and the Implementation Regulations on Labor Contract Law of the PRC which was promulgated and came into effect on September 18, 2008 by the State Council, seek to clarify the responsibilities of both employers and employees and codifies certain basic rights and protections of employees. Among others, the Labor Contract Law of the PRC provides that after completing two fixed-term employment contracts, an employee that desires to continue working for an employer is entitled to require a non-fixed-term employment contract. In addition, employees who have been employed for more than ten years by the same employer are entitled to require a non-fixed-term contract. The Labor Contract Law of the PRC also requires that the employees dispatched from human resources outsourcing firms or labor agencies be limited to temporary, auxiliary or substitute positions. Furthermore, where an employer causes any damage to the dispatched employee, the labor dispatch entity and the employer shall assume joint and several liabilities. According to the Interim Provisions on Labor Dispatch, which was promulgated in January 2014 and took effect in March 2014, to implement the provisions of the Labor Contract Law of the PRC regarding labor dispatch, a company is permitted to use dispatched employees for up to 10% of its labor force and the companies currently using dispatched employees are given a two-year grace period after March 1, 2014 to comply with this limit.

According to the Individual Income Tax Law of the PRC, which was promulgated on September 10, 1980 by the National People’s Congress, last amended by the SCNPC on August 31, 2018 and came into effect on January 1, 2019, companies operating in China are required to withhold individual income tax on employees’ salaries based on the actual salary of each employee upon payment. According to the Law on Social Insurance of the PRC, which was promulgated by the SCNPC on October 28, 2010, came into effect on July 1, 2011, and was amended on December 29, 2018, the Provisional Regulations on the Collection and Payment of Social Insurance Premium, which was promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund, which was promulgated by the State Council on April 3, 1999 and came into effect on the same date, and was amended on March 24, 2002 and March 24, 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and housing provident funds. Employers who fail to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

PRC regulations relating to employee stock incentive plan

In February 2012, the State Administration of Foreign Exchange, or SAFE, promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules. In accordance with the Stock Option Rules and relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan are subject to such regulation. In addition, the State Taxation Administration of the PRC has issued circulars concerning employee stock options or restricted shares. Under these circulars, employees working in China who exercise stock options, or whose restricted shares vest, will be subject to Chinese individual income tax, or IIT. The Chinese subsidiaries of an overseas listed company have obligations to file documents related to employee stock options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their stock options or restricted shares. If the employees fail to pay, or the Chinese subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the Chinese subsidiaries may face sanctions imposed by the tax authorities or other Chinese government authorities.

PRC regulations relating to dividend distribution

Pursuant to the PRC Company Law and Foreign Investment Law, and Regulations on Implementing the Foreign Investment Law of the PRC, foreign investors may freely remit into or out of China, in RMB or any other foreign currency, their capital contributions, profits, capital gains, income from asset disposal, intellectual property royalties, lawfully acquired compensation, indemnity or liquidation income and so on within the territory of China.

In January 2017, SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (1) under the principle of genuine transaction, banks must check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (2) domestic entities must hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

PRC regulations relating to foreign currency exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, 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 foreign currency-denominated loans.

The Circular on Reforming the Management Method regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or Circular 19, promulgated by the SAFE on March 30, 2015 and last amended on March 23, 2023, allows foreign-invested enterprises to make equity investments by using RMB funds converted from foreign exchange capital. Under Circular 19, the foreign exchange capital in the capital account of foreign-invested enterprises upon the confirmation of rights and interests of monetary contribution by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operation needs of the enterprises. The proportion of willingness-based foreign exchange settlement of capital for foreign-invested enterprises is temporarily set at 100%. The SAFE can adjust such proportion in due time based on the circumstances of the international balance of payments. However, Circular 19 and the Circular on Reforming and Regulating the Management Policies on the Settlement of Capital Projects, or Circular 16, promulgated by the SAFE on and effective as of June 9, 2016, continues to prohibit foreign-invested enterprises from, among other things, using RMB fund converted from its foreign exchange capitals for expenditure beyond its business scope, investment and financing in securities and other investments except for bank's principal-secured products, providing loans to non-affiliated enterprises or constructing or purchasing real estate not for self-use. Recently, Circular 16 has further been amended by Circular of the State Administration of Foreign Exchange on Further Deepening Reform and Promoting Cross-border Trade and Investment Facilitation issued by SAFE on December 4, 2023 to further clarify restrictions on the use of domestic institutions' income from foreign exchange receipts under capital account and the RMB funds obtained from the settlement.

On October 23, 2019, SAFE promulgated the Circular on Further Promoting the Facilitation of Cross-border Trade and Investment, or Circular 28. Pursuant to Circular 28, on the basis of allowing investment-oriented foreign-invested enterprise (including foreign-invested investment companies, foreign-invested venture capital enterprises and foreign-invested equity investment enterprises) to use capital funds for domestic equity investment in accordance with laws and regulations, non-investment foreign-invested enterprises will be allowed to use capital funds for domestic equity investment in accordance with the laws under the premise of not violating the Negative List and the authenticity and compliance of their domestic invested projects. Such provisions have recently been replaced by Circular on Further Deepening Reform and Promoting Cross-border Trade and Investment Facilitation that when non-investing foreign-funded enterprise makes domestic equity investment with capital funds in the domestic currency, the investee will handle the registration for the acceptance of domestic reinvestment and open a capital account to receive funds, and no entry registration of cash contribution is further required. The domestic institution that transfers the equity will, in accordance with the relevant provisions, register the receipt of domestic reinvestment and open a settlement account under the capital account to receive the consideration for equity transfer.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business issued by SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, with no need to provide the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use will be authentic and in line with provisions, and conform to the prevailing administrative regulations on the use of income under capital accounts. The concerned bank will conduct spot checking in accordance with the relevant requirements.

On December 25, 2006, the People's Bank of China issued the Administration Measures on Individual Foreign Exchange Control and its Implementation Rules were issued by SAFE on January 5, 2007, both of which became effective on February 1, 2007. The Implementation Rules was later partly amended on May 29, 2016, and March 23, 2023. Under these regulations, all foreign exchange matters involved in the employee stock ownership plan, stock option plan and other similar plans, participated by onshore individuals shall be transacted upon approval from SAFE or its authorized branch. On February 15, 2012, SAFE promulgated the Notice on Relevant Issues Concerning Foreign Exchange Control on Domestic Individuals Participating in the Stock Incentive Plan of An Overseas Listed Company, or Circular 7, to replace the Operating Procedures for Administration of Domestic Individuals Participating in the Employee Stock Option Plan or Stock Option Plan of An Overseas Listed Company. Under Circular 7, the board members, supervisors, officers or other employees, including PRC citizens and foreigners having lived within the territory of the PRC successively for at least one year of a PRC entity, who participate in stock incentive plans or equity compensation plans by an overseas publicly listed company, or the PRC participants, are required, through a PRC agent or PRC subsidiaries of such overseas publicly-listed company, to complete certain foreign exchange registration procedures with respect to the plans upon the examination by, and approval of, SAFE. We and our PRC participants who have been granted stock options are subject to Circular 7. If our PRC participants who hold such options or our PRC subsidiary fail to comply with these regulations, such participants and their PRC employer may be subject to fines and legal sanctions.

PRC regulations of commercial bribery

Pursuant to specific provisions in the amended PRC Anti-Unfair Competition Law effective from April 23, 2019, commercial bribery is prohibited. Both the bribe giver and bribe recipient are subject to civil and criminal liability. Further, pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry, which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for the establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant Chinese government authorities merely by virtue of having contractual relationships with distributors or third-party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third-party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third-party promoters, and it will not be subject to penalties or sanctions by relevant Chinese government authorities as a result of failure to monitor their operating activities.

PRC regulations of product liability

Along with the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in China. Under current PRC law, manufacturers and vendors of defective products in China may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the PRC, or PRC Civil Law, promulgated on April 12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. The Civil Code of the PRC, or PRC Civil Code, which was promulgated in May 2020 and became effective on January 1, 2021, amalgamates and replaces a series of specialized laws in civil law area, including the PRC Civil Law. The rules on product liability in the PRC Civil Code remain consistent with the rules in the PRC Civil Law.

On February 22, 1993, the Product Quality Law of the PRC, or Product Quality Law, was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised on July 8, 2000, August 27, 2009 and December 29, 2018 respectively. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. According to which, all business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

PRC tort law

Under the Tort Law of the PRC, or the Tort Law, which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as the issuance of a warning, or the recall of products in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages. The PRC Civil Code amalgamated and replaced the Tort Law effective January 1, 2021. The rules on tort in the PRC Civil Code are generally consistent with the Tort Law.

PRC regulations on cybersecurity review and data privacy

On November 7, 2016, the SCNPC issued the Cyber Security Law of the PRC, with the most recent amendment coming into effect on January 1, 2026. Pursuant to the Cyber Security Law of the PRC, network operators must not, without users' consent, collect their personal information, and may only collect users' personal information necessary to provide their services. Providers are also obliged to provide security maintenance for their products and services and shall comply with provisions regarding the protection of personal information as stipulated under the relevant laws and regulations. In addition, pursuant to the Cyber Security Law of the PRC, personal information and important data collected and generated by a critical information infrastructure operator, or CIIO, in the course of its operations in China must be stored in China, and if a CIIO purchases internet products and services that affects or may affect national security, it should be subject to cybersecurity review by the CAC.

In June 2021, the SCNPC promulgated the Data Security Law of the PRC, which took effect in September 2021. The Data Security Law of the PRC applies to data handling activities carried out within the territory of the PRC. The Data Security Law of the PRC further provides that data processing activities carried out outside of China, which harm national security, public interest or legal interests of Chinese citizens and organizations, should be subject to legal liabilities. Pursuant to the Data Security Law of the PRC, those conducting data handling activities should, in accordance with laws and regulations, establish and perfect a data security management system across their entire workflow and adopt the corresponding technical measures and other necessary measures to ensure data security.

In July 2021, the State Council promulgated the Regulations on the Security Protection of Critical Information Infrastructure, which came into effect on September 1, 2021 and further clarified the definition of critical information infrastructure. Under such regulations, critical information infrastructure refers to the important network facilities and information systems in crucial industries and fields such as public telecommunications, information services, energy, transportation, water conservancy, finance, public services, e-government and national defense science, technology and industry, as well as other important network facilities and information systems which, in case of destruction, loss of function or leak of data, may result in serious damage to national security, national economy, the people's livelihood and public interests. According to such regulations, a CIIO is required to perform certain obligations to protect the critical information infrastructure's security, including but not limited to, conducting network security tests and risk assessments at least once a year.

The security protection departments are responsible for organizing the identification of CIIOs in their respective industries and areas in accordance with the identification rules and shall inform the identification results to the operators of network facilities and information systems in a timely manner and in the meanwhile report such results to the public security department of the State Council.

In December 2021, the CAC and related authorities promulgated the Cybersecurity Review Measures, or the Cybersecurity Measures, which took effect on February 15, 2022. According to the Cybersecurity Measures, a company is subject to cybersecurity review if it affects or may affect national security and falls under any of the following circumstances: (1) it is a CIIO who purchases network products and service, or (2) it is a network platform operator who carries out data processing activities. In addition, any network platform operator possessing over one million users' personal information must apply for a cybersecurity review before listing abroad. Relevant PRC regulatory authorities may also initiate cybersecurity review if they determine certain network products, services, or data processing activities affect or may affect national security.

The Personal Information Protection Law, or the PIPL, which took effect on November 1, 2021, outlines the main system framework and comprehensive requirements for personal information processing. The PIPL provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The PIPL also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the PIPL contains proposals for significant fines for serious violations of up to RMB50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities.

On March 22, 2024, the CAC enacted the Provisions on Promoting and Regulating Cross-Border Data Flows, or the Cross-Border Data Flows Provisions, further regulating that a data processor's responsibility to conduct cybersecurity review such as applying for the data export security assessment, submitting the standard contract filing, or obtaining the compliance certification can be exempted under certain circumstances, including, among others: (1) an individual's information must be provided abroad for entering into or performing a contract which the individual is a contracting party, such as for cross-border shopping, cross-border delivery, cross-border remittance, cross-border payment, cross-border account opening, air ticket and hotel reservation, visa processing and examination services; (2) an employee's information must be provided abroad for human resource management under the labor-relating rules and regulations and a collective contract signed in accordance with the law; (3) an individual's information that must be provided abroad to protect the safety of his/her life and property under emergency circumstances; and (4) the cumulative number of the individuals' information that a data processor (other than CIIO) transferred abroad in a year since January 1 is smaller than 100,000 individuals and no sensitive personal information is included.

PRC regulations on securities offering and listing outside of China

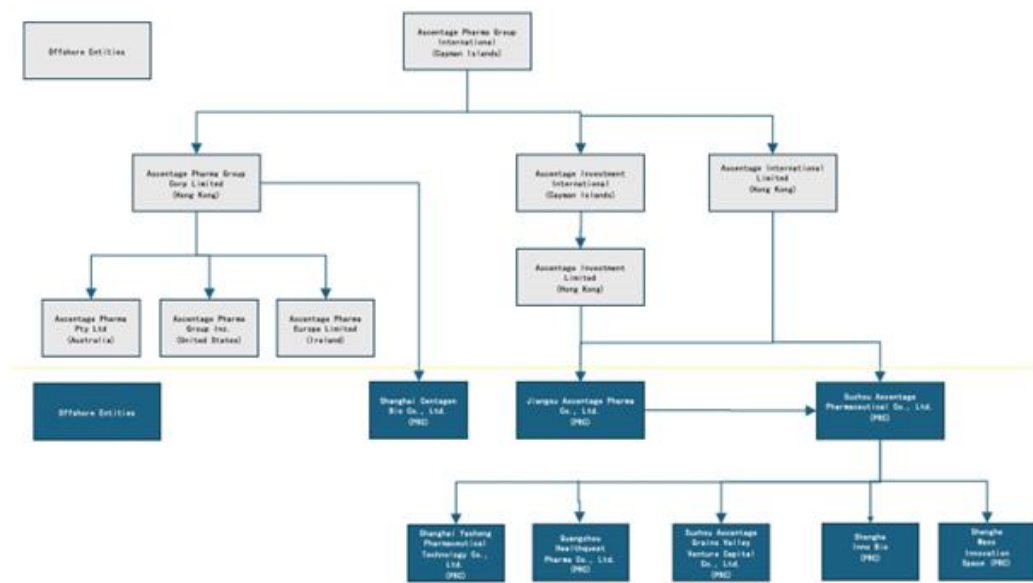
On February 17, 2023, the China Securities Regulatory Commission promulgated the Trial Measures, and relevant notes and supporting guidelines, which came into effect on March 31, 2023. The Trial Measures seek to regulate all types of overseas offerings and listings by PRC based companies, including: (a) direct overseas listings, i.e. overseas listings by joint-stock companies which are established in PRC; and (b) indirect overseas listings, i.e. overseas listings by PRC based companies in the names of an overseas entity, if such issuers meets both of the following conditions: (1) more than 50% of its audited financial indicators (either operating revenue, profits, total assets or net assets) for the most recent accounting year is accounted for by its PRC-based companies, and (2) major business activities or operations are conducted within the territory of PRC; main places of business are located within the territory of the PRC; or the majority of senior management staff domicile in the PRC or are Chinese citizens.

Meanwhile, overseas offering and listing would be prohibited under certain circumstances, including but not limited to (1) the offering and listing are expressly forbidden by the Chinese laws, regulations and relevant rules; (2) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws or (3) there are material disputes with regard to the ownership of the equity held by the domestic company's controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller. If a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the domestic company will postpone or terminate the intended overseas offering and listing, and report to the CSRC and competent authorities under the State Council in a timely manner. If domestic companies fail to fulfill the above-mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they would be warned and fined up to RMB10 million. The controlling shareholders and actual controllers of such domestic companies that organize or instruct the aforementioned violations would be fined up to RMB10 million and directly liable persons-in-charge and other directly liable persons would be each fined up to RMB5 million.

On February 24, 2023, the CSRC, the Ministry of Finance, the National Administration of State Secrets Protection and the National Archives Administration jointly issued the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies, or the Confidentiality and Archives Provisions, which became effective from March 31, 2023. The Confidentiality and Archives Provisions specify that during the overseas issuance of securities and listing activities of domestic enterprises, domestic enterprises and securities companies and securities service institutions that provide relevant securities services will, by strictly abiding by the relevant laws and regulations of the PRC and the requirements therein, establish sound confidentiality and archives management systems, take necessary measures to implement confidentiality and archives management responsibilities, and will not leak national secrets, work secrets of governmental agencies and undermine national and public interests. Work manuscripts generated in the PRC by securities companies and securities service institutions that provide relevant securities services for overseas issuance and listing of securities by domestic enterprises will be kept in the PRC. Without the approval of relevant competent authorities, it will not be transferred overseas. Where archives or copies need to be transferred outside of the PRC, it will be subject to the approval procedures in accordance with relevant PRC regulations.

C. Organizational Structure

The following diagram illustrates our corporate structure, including our principal subsidiaries, categorized into onshore entities, which are organized and registered in the PRC, and offshore entities, which are organized and registered outside of the PRC, as of the date of this Annual Report on Form 20-F:



We do not currently use, and have not used in the past, a variable interest entity structure.

On March 2026, the Board approved the transfer of ownership by Ascentage Pharma Group Corp Limited of Ascentage Pharma Group Inc., Ascentage Pharma Pty Ltd. and Ascentage Pharma Europe Limited to Ascentage Pharma Group International to streamline the organization. Once the transfer is completed, these three subsidiaries will be directly owned by Ascentage Pharma Group International and thus in the organization chart above will appear directly under Ascentage Pharma Group International connected by a solid line and arrow.

D. Property, Plants and Equipment

Our corporate headquarters are located in Suzhou and consists of more than 200,000 square feet of leased space. This facility currently accommodates half of our executive leadership team and leadership of our product and technology, marketing, sales and corporate functions, as well as our R&D center and manufacturing facility.

We also lease offices in Shanghai, Suzhou, Guangzhou, Taizhou and Beijing in China and Rockville, Maryland in the United States. We believe that our facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations. See “Item 4. Information on the Company—B. Business Overview—Manufacturing and facilities.”

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this Annual Report on Form 20-F. This discussion contains forward-looking statements that reflect our plans, estimates, and beliefs that involve risks and uncertainties. As a result of many factors, such as those set forth under the “*Item 3. Key Information—D. Risk Factors*” and “*Cautionary Note Regarding Forward-Looking Statements*” sections and elsewhere in this Annual Report on Form 20-F, our actual results may differ materially from those anticipated in these forward-looking statements.

For a discussion of our results in the year ended December 31, 2024 compared to the year ended December 31, 2023 and certain financial information as of December 31, 2023, please refer to the section titled “*Item 5. Operating and Financial Review and Prospects*” contained in our Annual Report on Form 20-F for the year ended December 31, 2024, filed with the SEC on April 16, 2025.

A. Operating Results

We are a global, integrated biopharmaceutical company engaged in discovery, development and commercializing therapies to address global unmet medical needs primarily in hematological malignancies. For more than two decades, our founders and team have leveraged their deep expertise to develop our proprietary drug discovery platform to pursue particularly challenging targets and significant unmet global medical needs. Our lead assets, Olverembatinib and Lisoftoclax, have global potential to address the major hematological malignancies, including chronic myeloid leukemia, or CML, acute myeloid leukemia, or AML, chronic lymphocytic leukemia, or CLL, acute lymphocytic leukemia, or ALL, myelodysplastic syndrome, or MDS, and multiple myeloma, or MM, which is expected to exceed US\$166 billion in aggregate market size by 2035, according to the F&S Report. According to the F&S Report, we are the only company in the world with active clinical programs targeting all three known classes of key apoptosis regulators. We have nine ongoing U.S. and/or international registrational trials, including four that are FDA-regulated, for our two key clinical-stage assets.

As a research intensive, innovation-focused company, we have also incurred losses and experienced negative operating cash flows since inception. Our net loss was RMB1,243.0 million (US\$177.7 million), RMB405.7 million and RMB 925.7 million for the years ended December 31, 2025, 2024 and 2023, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we conduct our ongoing and planned preclinical studies and clinical trials, continue our research and development activities and seek regulatory approvals for our product candidates, obtain and protect our intellectual property and incur additional costs to establish sales, marketing and distribution infrastructure for expanding sales or to commercialize any product candidate for which we may obtain regulatory approval in the future. We will also incur increased audit, legal, regulatory and compliance costs as well as investor and public relations expenses associated with operating as a public company both in Hong Kong and in the United States.

Strategic partnership with Innovent

In July 2021, we entered into a strategic partnership with Innovent pursuant to a collaboration and license agreement among Ascentage Pharma Group Corp Limited, Innovent and Guangzhou Healthquest Pharma Corp. Limited, or the HQP1351 Collaboration and License Agreement. Under the HQP1351 Collaboration and License Agreement, we granted to Innovent development and commercialization rights (including branding rights) for Olverembatinib and any finished form product comprising Olverembatinib, or the Licensed Products. Pursuant to the HQP1351 Collaboration and License Agreement, Innovent paid us an upfront payment of US\$30 million, and upon achievement of certain regulatory and commercial milestones Innovent is obligated to make milestone payments of up to an additional US\$115 million in the aggregate. We and Innovent have also agreed to use commercially reasonable efforts to carry out development and commercialization of the Licensed Products in the Field and for the Territory. For additional information regarding the HQP1351 Collaboration and License Agreement “*Item 4. Information on the Company—B. Business Overview—Strategic partnership with Innovent.*”

Components of results of operations

Revenue

Revenue primarily consists of (1) sales of pharmaceutical products, (2) income relating to commercialization rights pursuant to the HQP1351 Collaboration and License Agreement (3) management fee income of fund and (4) intellectual property income. Revenue from sales of pharmaceutical products is generally recognized at the point in time when control of the product is transferred to the customer, generally on acceptance of the products. Income relating to commercialization rights pursuant to the HQP1351 Collaboration and License Agreement is recorded under contract liabilities and recognized over time during the expected commercialization period, after we obtain commercialization authorization from local authorities. Income relating to commercialization rights includes both a fixed element (the initial payment) and variable elements (including but not limited to development milestones and commercialization milestones). Milestone payments pursuant to the HQP1351 Collaboration and License Agreement are recognized as performance obligations are satisfied, once we can conclude that it is highly probable that there will not be a subsequent reversal of a significant amount of revenue. The intellectual property income is recognized at a point of time upon the customer obtains the right to use the non-patented intellectual property as there are no ongoing activities that significantly affect intellectual property.

Cost of sales

Cost of sales primarily consists of commissioned processing costs of Olverembatinib and Liasftoclax, costs relating to the purchase of other products, product packaging and delivery costs and patent amortization costs for sales-based royalties.

Other income and gains

Other income and gains primarily consist of income from government grants, fair value gain on derivative financial instruments and interest income on term deposit at banks. Income from government grants is conditioned on use for research and development projects, which grants are intended to compensate expenses arising from research activities and clinical trials, and incentivize the development of new drugs. Income from government grants is recognized as profit upon our receipt of acknowledgment of compliance from the relevant governmental body.

Fair value gain on derivative financial instruments consists of the fair value gain on the warrants issued to Innovent pursuant to the warrant subscription deed entered into on July 14, 2021. These warrants expired in July 2023 without having been exercised.

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 a financial instrument, or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Operating expenses

Selling and distribution expenses

Selling and distribution expenses primarily consist of marketing expenses, employee-related expenses, and travel and meeting expenses.

Research and development expenses

Research and development expenses primarily consist of internal and external research and development expenses, including clinical trial expenses incurred to develop our drug candidates, CRO-related expenses, costs of materials to support our clinical trials and preclinical studies and costs associated with preclinical activities, staff costs, intellectual property expenses, materials, depreciation and amortization and share option and RSU expenses of research and development employees.

Since inception, we have dedicated significant resources to our research and development activities. For the years ended December 31, 2025 and 2024, our research and development expenses represented 61.0% and 67.5%, respectively, of our total operating expenses. As we initiate new clinical trials and continue to advance our clinical programs for our drug candidates, we expect our research and development expenses to continue to increase for the foreseeable future and to remain a significant percentage of our total operating expenses.

The following table sets forth the components of our research and development expenses by nature for the periods indicated.

	Year ended December 31,		
	2025	2025	2024
	RMB	US\$	RMB
	(in thousands)		
Internal and external research and development expenses	634,700	90,761	493,766
Employee-related expenses and share option and RSU expenses related to R&D employees	376,412	53,826	336,059
Depreciation and amortization	23,868	3,413	33,439
Intellectual property, materials expenses and other expenses	102,468	14,653	83,981
Total	1,137,448	162,653	947,245

The following table sets forth the components of our external research and development expenses by compound for the periods indicated.

	Year ended December 31,		
	2025	2025	2024
	RMB	US\$	RMB
	(in thousands)		
APG-2575 CMC and clinical expense	395,871	49,123	358,565
HQP1351 CMC and clinical expense	188,059	11,175	81,571
APG-115 CMC and clinical expense	13,482	3,110	22,702
APG-5918 CMC and clinical expense	11,063	499	3,639
APG-1252 CMC and clinical expense	2,720	1,349	9,845
Other pipelines' CMC and clinical expense	20,083	1,412	10,304
Total external research and development expenses	631,278	66,668	486,626

Administrative Expenses

Administrative expenses consist primarily of share option and RSU expenses, employee-related expenses and depreciation, and amortization.

We expect our general and administrative expenses to increase as we have increased our headcount over the past year and expect to increase our headcount in the immediate future. However, we will incur increased audit, legal, regulatory and compliance costs as well as investor and public relations expenses associated with operating as a public company both in Hong Kong and the United States.

The following table sets forth the components of our administrative expenses for the periods indicated.

	Year ended December 31,		
	2025	2025	2024
	RMB	US\$ (in thousands)	RMB
Share option and RSU expenses	4,017	574	2,861
Employee-related expenses	94,608	13,529	63,081
Depreciation and amortization	47,004	6,721	51,356
Others	100,652	14,394	69,827
Total	246,281	35,218	187,125

Finance costs

Finance costs primarily consist of interest expenses from bank borrowings and other borrowings.

Other Expenses

Other expenses primarily consist of fair value loss on financial assets at fair value through profit or loss, or FVTPL, and donations. The loss on fair value of the financial assets at FVTPL was a non-cash adjustment that represented the change in fair value arising from the common stock of Unity Biotechnology, Inc. held by us. We had entered into several agreements with Unity, covering the development and commercialization of certain Bcl-2/Bcl-xL inhibitors, including APG-1252 and APG-1197, respectively. Since that time, Unity has ceased operations. Donations primarily consist of the cost of sponsoring academic events of associations and foundations for public charitable purposes.

Share of profit of a joint venture

We share profits in venture capital investments through our 33.42% equity interest in Suzhou Ascentage Harvest Venture Capital LLP, or Ascentage Harvest. Ascentage Harvest is a venture capital firm that invests in and incubates unlisted high-quality early stage biomedical innovation companies.

Income tax

We are subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which we and our subsidiaries are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, Ascentage Pharma Group International is not subject to tax on income or capital gain arising in the Cayman Islands. Additionally, upon payments of dividends by Ascentage Pharma Group International to its shareholders, no Cayman Islands withholding tax will be imposed.

Hong Kong

Subsidiaries incorporated in Hong Kong are subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong. For the years ended December 31, 2025 and 2024, Ascentage Pharma Group International did not make any provisions for Hong Kong profits tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented.

Chinese mainland

The Company's subsidiaries domiciled in the PRC are subject to the statutory rate of 25%, in accordance with the Enterprise Income Tax law (the "EIT Law"), which was effective since 1 January 2008, except for the following entities which are eligible for a preferential tax rate.

Healthquest Pharma was qualified as a High and New Technology Enterprise ("HNTE") and was subject to a preferential rate of 15% for three years from 2022 to 2024. In 2025, Healthquest Pharma was no longer qualified as a HNTE and thus subject to the statutory tax rate of 25%.

Suzhou Yasheng was recognized as a qualified HNTE under the EIT Law by the relevant government authorities and is subject to a preferential rate of 15% for three years from 2023 to 2025.

United States

The subsidiary operating in the United States is subject to tax at a maximum of 21.61% and 21.36%, respectively, for the years ended 31 December 2025 and 2024. No provision for income tax has been made as the Group had no assessable profits earned in the United States during the reporting period.

A requirement to capitalize and amortize previously deductible research and experimental expenses resulting from a change in Section 174 made by the Tax Cuts and Jobs Act of 2017 (the "TCJA") became effective on 1 January 2022. Under the TCJA, the Company is required to capitalize and subsequently amortize R&D expenses over five years for research activities conducted within the U.S and fifteen years for research activities conducted outside of the U.S.

In July 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, which reinstated current deductibility of domestic research and experimental expenditures and provided an election to accelerate the recovery of previously capitalized costs. The Company did not elect to accelerate the deduction of previously capitalized domestic research and experimental expenditures and will continue to amortize such costs over the remaining statutory periods.

Results of operations

Comparison of years ended December 31, 2025 and 2024

	Year ended December 31,		
	2025	2025	2024
	RMB	US\$	RMB
	(in thousands)		
Revenue	574,120	82,098	980,650
Cost of sales	(48,938)	(6,998)	(29,085)
Gross profit	525,182	75,100	951,565
Other income and gains	103,495	14,800	57,359
Selling and distribution expenses	(353,640)	(50,570)	(195,998)
Research and development expenses	(1,137,448)	(162,653)	(947,245)
Administrative expenses	(246,281)	(35,218)	(187,125)
Finance costs	(54,070)	(7,732)	(64,455)
Other expenses	(73,599)	(10,525)	(9,075)
Share of profit/(loss) of a joint venture	314	45	(281)
Loss before tax	(1,236,047)	(176,753)	(395,255)
Income tax expense	(6,940)	(992)	(10,425)
Loss for the year	(1,242,987)	(177,745)	(405,680)

Revenue

For the year ended December 31, 2025, we generated revenue of RMB574.1 million (US\$82.1 million) from the sales of pharmaceutical products, commercialization rights income from Innovent and management fee income compared to RMB980.7 million for the year ended December 31, 2024, representing a decrease of RMB406.6 million, or 41.5%, which was primarily attributable to the intellectual property income from Takeda in 2024 partially offset by the rise in sales of pharmaceutical products.

Cost of sales

Cost of sales for the year ended December 31, 2025 was RMB48.9 million (US\$7.0 million), compared to RMB29.1 million for the year ended December 31, 2024, representing an increase of RMB19.8 million, or 68.3%, primarily due to the increase in the production cost of Lixaftoclax and Olverembatinib.

Other income and gains

Other income and gains for the year ended December 31, 2025 was RMB103.5 million (US\$14.8 million), compared to RMB 57.4 million for the year ended December 31, 2024, representing an increase of RMB46.1 million, or 80.4%, which was primarily attributable to (i) the increase in bank interest income to RMB82.1 million (US\$11.7 million) for the year ended December 31, 2025, as compared to RMB37.8 million for the year ended December 31, 2024; (ii) the increase in government grants related to income to RMB14.5 million (US\$2.1 million) for the year ended December 31, 2025, as compared with RMB9.1 million for the year ended December 31, 2024; and (iii) the increase in rental income to RMB5.0 million (US\$0.7 million) for the year ended December 31, 2025, as compared with RMB2.3 million for the year ended December 31, 2024.

Operating expenses

Selling and distribution expenses

For the year ended December 31, 2025, the selling and distribution expenses increased by RMB157.6 million or 80.4% to RMB353.6 million (US\$50.6 million), as compared to RMB 196.0 million for the year ended December 31, 2024. The increase was attributable to the increase in selling and distribution expenses incurred in the commercialization of Lixaftoclax and Olverembatinib.

Research and development expenses

For the year ended December 31, 2025, the research and development expenses increased by RMB190.2 million, or 20.1% to RMB1,137.4 million (US\$162.7 million) from RMB 947.2 million for the year ended December 31, 2024. The increase was attributable to the increase in clinical research expenses.

Administrative expenses

For the year ended December 31, 2025, the administrative expenses increased by RMB59.2 million, or 31.6% to RMB246.3 million (US\$35.2 million) from RMB 187.1 million for the year ended December 31, 2024. The increase was primarily attributable to the increased staff cost.

Finance Costs

For the year ended December 31, 2025, the finance costs decreased by RMB10.4 million, or 16.1% to RMB54.1 million (US\$7.7 million) from RMB 64.5 million for the year ended December 31, 2024. It was due to the decrease of the interest rate incurred in relation to bank borrowings.

Other Expenses

For the year ended December 31, 2025, other expenses were RMB73.6 million (US\$10.5 million), as compared to other expenses of RMB9.1 million for the year ended December 31, 2024, which represented an increase of RMB64.5 million, or 711.0%. The increase was primarily attributable to (i) the increase in fair value loss of contingent acquisition consideration related to the acquisition of Guangzhou Healthquest Pharma Co., Ltd. in December 2016 to RMB29.5 million (US\$4.2 million) in 2025, and (ii) the increase in donations to RMB23.4 million (US\$3.3 million) for the year ended December 31, 2025, as compared to RMB6.3 million for the year ended December 31, 2024.

The loss on fair value of the financial assets at FVTPL was a non-cash adjustment that represented the change in fair value arising from the common stock of Unity held by us.

Share of profit/(loss) of a joint venture

For the year ended December 31, 2025, share of profit of a joint venture was RMB0.3 million (US\$0.05 million), compared to a loss of RMB0.3 million for the year ended December 31, 2024.

Loss for the reporting period

The loss of the Company increased by RMB837.3 million, or 206.4%, to RMB1,243.0 million (US\$177.7 million) for the year ended December 31, 2025 from RMB405.7 million for the year ended December 31, 2024.

Income tax expense

For the year ended December 31, 2025, income tax expense was RMB6.9 million (US\$1.0 million), compared to RMB10.4 million of income tax expense for the year ended December 31, 2024, representing a decrease of RMB3.5 million, or 33.4%.

B. Liquidity and Capital Resources

Our operations have historically been financed primarily by capital increases from our founders and investors and net proceeds from our public and private financings. Although we have commercialized Olverembatinib in the PRC, we have incurred significant net losses in the past, and we intend to continue to invest substantially in our business. As a result, we may not be able to achieve or sustain profitability in the future. Until such time as we can generate significant revenue from product sales, we expect to finance our operations through equity sales, debt financings and other capital sources, including potential collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. We may be unable to raise additional funds or enter into other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of one or more of our product candidates, which could have a material adverse effect on our business, results of operations or financial condition. In addition, our net losses may fluctuate significantly from period to period, depending upon the timing of our expenditures on our research and development activities.

As of December 31, 2025 and 2024, we had cash and bank balances of RMB2,470.1 million (US\$353.2 million) and RMB1,261.2 million, respectively. Our principal sources of liquidity are cash and bank balances and interest-bearing bank and other borrowings. We place cash and cash equivalents (which are mostly held in U.S. dollars, Hong Kong dollars and RMB) in short term deposits with authorized institutions in Hong Kong and China.

Our ordinary shares were listed on the HKEx in 2019, and the net proceeds from our initial public offering on the HKEx (including shares issued as a result of the full exercise of the over-allotment option) were approximately HK\$369.8 million (US\$47.5 million). Since 2024, we have also raised proceeds in the transactions described below.

In June 2024, we entered into an exclusive option agreement, or the Takeda Exclusive Option Agreement, with Takeda Pharmaceuticals International AG, or Takeda, and our affiliates, Guangzhou Healthquest Pharma Co., Ltd. and Ascentage Pharma (Suzhou) Co., Ltd. Pursuant to the Takeda Exclusive Option Agreement, Takeda paid us US\$100.0 million. In aggregate, under the Takeda Exclusive Option Agreement and the expected terms of the exclusive license agreement, we are eligible to be paid a one-time option exercise fee and certain development, commercial and sales milestones up to approximately US\$1.2 billion and royalties in a range equal to 12-19% of net sales. In addition, in June 2024, we issued and sold to Takeda 24,307,322 ordinary shares, or the Takeda Shares, for an aggregate purchase price of US\$75 million.

In January 2025, we completed our U.S. initial public offering in which we offered and sold an aggregate 7,325,000 ADSs at an offer price of US\$17.25 per ADS, representing 29,300,000 ordinary shares of the Company for gross proceeds of approximately US\$126.4 million (equivalent to approximately HK\$983.8 million). On February 13, 2025, in connection with the underwriters' exercise of their over-allotment option, we issued an additional 935,144 ADSs at an offer price of US\$17.25 per ADS, representing 3,740,576 ordinary shares of the Company for gross proceeds of approximately US\$16.13 million (equivalent to approximately HK\$125.6 million). Each ADS represents 4 ordinary shares. Our ADSs are listed on the Nasdaq Global Market, or the Nasdaq, under the symbol "AAPG."

In 2025, we entered into the 2025 Placing and Subscription Agreement with Dajun Yang Dynasty Trust, a family trust established by Dr. Yang, as vendor, and J.P. Morgan Securities (Asia Pacific) Limited and Citigroup Global Markets Limited, as placing agents. An aggregate of 22,000,000 existing ordinary shares owned by the vendor were placed by the placing agents to not less than six placees at a price of HK\$68.60 per share and we subsequently issued to the vendor the same number of 22,000,000 new ordinary shares of the Company at the same price of HK\$68.60 per share. The closing price of our ordinary shares on the HKEx on July 14, 2025, the date on which the terms of the top-up placing was fixed, was HK\$74.70. The net proceeds (after deducting all applicable costs and expenses, including commission and levies) raised were HK\$1,492.5 million (US\$190.1 million).

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 20-F, but may not be sufficient for us to fund any of our drug candidates through regulatory approval, which may last several years. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Our present and future funding requirements may change and will depend on many factors. See *"Item 3. Key Information—D. —Risks related to our financial position and need for additional capital—We will need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates, including Olverembatinib and Lisoftoclax."*

Because of the numerous risks and uncertainties associated with product 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 additional revenue from product sales, 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 be forced to reduce or terminate our operations. See *"Item 3. Key Information—D. Risk Factors—Risks related to our financial position and need for additional capital—We have incurred significant net losses in the past, and we intend to continue to invest substantially in our business. As a result, we may not be able to achieve or sustain profitability in the future despite the commercialization of Olverembatinib in China."*

We expect our operating expenses to increase over the next several years as we expand our research and development activities. Until such time as we can generate significant revenue from product sales or royalties, if ever, we expect to finance our operations through a combination of public or private equity and debt financings or other sources, including payments upon achievement of certain development, regulatory and sales milestone events and royalty payments under our existing strategic agreements, and future collaborations with other third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest may be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt financing, if available and on commercially reasonable terms, may involve agreements that include 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 product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

Net cash used in operating activities

For the year ended December 31, 2025, net cash used in operating activities was RMB1,174.1 million (US\$167.9 million), which was primarily due to our loss before tax of RMB1,236.0 million (US\$176.8 million), adding back non-cash charges of RMB205.5 million (US\$29.4 million), including depreciation and amortization of assets, share option and RSU expenses and interest expenses from bank borrowings and other borrowings, and net cash used in changes in our operating assets and liabilities of RMB143.6 million (US\$20.5 million).

For the year ended December 31, 2024, net cash used in operating activities was RMB111.4 million, which was primarily due to our loss before tax of RMB395.3 million, adding back non-cash charges of RMB172.9 million, including depreciation and amortization of assets, share option and RSU expenses and interest expenses from bank borrowings and other borrowings, and net cash used in changes in our operating assets and liabilities of RMB111.0 million.

Net cash used in investing activities

For the year ended December 31, 2025, net cash used in investing activities was RMB1,000.1 million (US\$143.0 million), which primarily consisted of a net increase in property, plant and equipment and other intangible assets of RMB27.6 million (US\$3.9 million), and payment of contingent consideration in relation to our acquisition of Healthquest Pharma in December 2016 of RMB43.3 million (US\$6.2 million) and the increase in time deposits with original maturity of more than three months to RMB925.1 million (US\$132.3 million).

For the year ended December 31, 2024, net cash used in investing activities was RMB362.0 million, which primarily consisted of a net increase in property, plant and equipment and other intangible assets of RMB24.3 million, and an increase in time deposits with original maturity of more than three months of RMB312.2 million, as well as investment in a joint venture of RMB16.0 million.

Net cash provided by financing activities

For the year ended December 31, 2025, net cash inflows from financing activities of the Group amounted to RMB2,540.1 million (US\$363.2 million), which mainly consisted of net proceeds of RMB2,304.9 million (US\$329.6 million) from the U.S.IPO and the 2025 placing; partially offset by payments of interest paid which amounted to RMB51.3 million (US\$7.3 million).

For the year ended December 31, 2024, net cash provided by financing activities was RMB314.8 million, which primarily consisted of net proceeds of RMB533.9 million from the issuance of shares through our offering of ordinary shares in 2024, partially offset by payments of interest and lease principal of RMB69.0 million and payments of listing expenses of RMB13.3 million.

Contractual obligations and loans

As of December 31, 2025 and 2024, we had interest-bearing bank and other borrowings of RMB1,979.7 million (US\$283.1 million) of which lease liabilities comprised RMB22.2 million (US\$3.2 million), and RMB 1,668.5 million of which lease liabilities comprised RMB 30.2 million, respectively. The following table sets forth aggregate information about material contractual obligations and loans as of December 31, 2025 and 2024.

	As of December 31, 2025				As of December 31, 2024		
	Effective interest rate per annum	Maturity	RMB	US\$	Effective interest rate per annum	Maturity	RMB
	(%)		(in thousands)				(in thousands)
Current							
Short-term borrowing	2.11-2.50 or 1 year LPR-0.60 to 0.89	2026	1,040,000	148,718	2.60-2.70 or 1 year LPR-0.30 to 0.75	2025	290,000
Current portion of long term bank loans-unsecured	1 year LPR-0.45 to 0.75	2026	156,200	22,336	1 year LPR-0.15 to 0.65 or 1 year LPR+0.65 to 0.85	2025	213,170
Current portion of long term bank loans-unsecured	2.8	2026	2,500	358	2.80-4.55	2025	255,000
Current portion of long-term bank loans-secured	5 year LPR-0.85	2026	16,498	2,359	5 year LPR-0.85	2025	11,453
Lease liabilities	4.00-4.35	2026	7,283	1,041	4.00-4.35	2025	9,439
Total-current			1,222,481	174,812			779,062
Non-current							
Bank loans-unsecured	1 year LPR-0.45 to 0.75	2027 - 2028	114,900	16,431	1 year LPR-0.45 to 0.65 or 1 year LPR+0.70 to 0.85	2026-2028	203,100
Bank loans-unsecured	2.8	2027	43,750	6,256	2.80-4.50	2026-2027	77,250
Bank loans-secured*	5 year LPR-0.85	2027 - 2038	583,675	83,464	5 year LPR-0.85	2026-2038	588,292
Lease liabilities	4.00-4.35	2027 - 2028	14,913	2,133	4.00-4.35	2026-2028	20,793
Total-non-current			757,238	108,284			889,435
Total			1,979,719	283,096			1,668,497

Note: LPR represents the Loan Prime Rate.

* As of December 31, 2025, bank loans amounting to RMB600.2 million (US\$85.8 million) were secured by the pledge of our buildings with a net carrying amount of RMB677.0 million (US\$96.8 million) and right-of-use assets with a net carrying amount of RMB25.3 million (US\$3.6 million). Such loans were also guaranteed by two of our subsidiaries. As of December 31, 2024, bank loans amounting to RMB599.7 million were secured by the pledge of our buildings with a net carrying amount of RMB 731.3 million, and right-of-use assets with a net carrying amount of RMB26.5 million. Such loans were also guaranteed by two of our subsidiaries.

The unsecured bank loans amounting to RMB140.0 million (US20.0 million) and RMB278.1 million were guaranteed by our subsidiaries as of December 31, 2025 and 2024, respectively.

The following table sets forth the maturity analysis of our interest-bearing bank and other borrowings as of December 31, 2025 and 2024:

	As of December 31,		
	2025	2025	2024
	RMB	US\$ (in thousands)	RMB
Analyzed into:			
Within one year	1,222,481	174,812	779,062
In the second year	160,201	22,908	242,473
In the third to fifth years, inclusive	140,100	20,034	159,355
Beyond five years	456,937	65,342	487,607
Total	1,979,719	283,096	1,668,497

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

For a discussion of our research and development activities, see “*Item 4. Information on the Company—B. Business Overview*” and “*—A. Operating Results.*”

D. Trend Information

For a discussion of trends, see “*—A. Operating Results*” and “*—B. Liquidity and Capital Resources.*”

Other than as disclosed elsewhere in this Annual Report on Form 20-F, we are not aware of any trends, uncertainties, demands, commitments or events for the year ended December 31, 2025 that are reasonably likely to have a material and adverse effect on our revenues, income, profitability, liquidity or capital resources, or that would cause the financial information included in this Annual Report on Form 20-F to be not necessarily indicative of future results of operations or financial condition.

E. Critical accounting estimates

Income tax

Income tax is comprised of 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 each of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which us operate.

Deferred tax is provided, using the liability method, on all temporary differences at the end of reporting date 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:

(i) 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 does not give rise to equal taxable and deductible temporary differences; and

(ii) in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, and 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:

(i) 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 does not give rise to equal taxable and deductible temporary differences; and

(ii) in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognized to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at the end of each reporting period 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 we have 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 realize 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.

Revenue recognition

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which we will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until 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.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between us and the customer at contract inception. When the contract contains a financing component which provides us with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sale of products

Revenue from the sale of products is recognized at the point in time when control of the asset is transferred to the customer, generally on acceptance of the products.

(b) Commercialization rights

We provide commercialization, development and branding rights (collectively, “Commercialization Rights”) to customers for an agreed upon commercialization period ending ten years from the date of the first sale of the product as stipulated in the relevant agreement. The consideration for Commercialization Rights include upfront payment, development and regulatory milestones payments and commercialization milestones payments.

Development and regulatory milestones payments are fully constrained until the period in which those regulatory approvals are achieved due to the inherent uncertainty with the approval process and included in the transaction price in the period regulatory approval is obtained. Upfront payment and development and regulatory milestones payments are recorded under contract liabilities and recognized as revenue over time during the commercialization period on a straight-line basis.

Commercialization milestone payments based on the level of sales are recognized at a point in time when the later of the following events occurs: (i) the related sale occurs, or (ii) the performance obligation to which commercialization milestones payments have been allocated has been satisfied.

(c) Intellectual property income

Intellectual property income is recognized at the point in time at which the non-patented intellectual property is granted to the customer because we will not undertake activities that affect such intellectual property.

The consideration for intellectual property income comprises a fixed element and a variable element. Variable element is recognized as transaction price when we can conclude that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

(d) Others

We provide consulting and promotional services to our customers through contracts. Depending on the contract, revenue is recognized over time as the service is rendered, or at the point in time as the service is completed and accepted.

Other estimates

In addition to the critical accounting estimates described above, there are other accounting estimates within our consolidated financial statements. Management believes the current assumptions and other considerations used to estimate amounts reflected in our consolidated financial statements are appropriate. However, if actual experience differs from the assumptions and other considerations used in estimating amounts reflected in our consolidated financial statements, the resulting changes could have a material adverse effect on our consolidated results of operations or financial condition. See Note 3 to the consolidated financial statements for further information on significant accounting policies that impact us.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and senior management

The following table sets forth certain information relating to our executive officers and directors as of date of this Annual Report on Form 20-F.

Name	Age	Position(s)
Executive Officers		
Dajun Yang, M.D., Ph.D.	64	Chairman, Chief Executive Officer and Director
Yifan Zhai, M.D., Ph.D.	65	Chief Medical Officer
Veet Misra, Ph.D.	54	Chief Financial Officer
Thomas J. Knapp	73	SVP, General Counsel
Jin Cao	39	Head of Finance, China
Non-Employee Directors		
Marina S. Bozilenko ⁽¹⁾	59	Director
Marc E. Lippman, M.D. ⁽²⁾⁽⁴⁾	80	Director
Simon Dazhong Lu, Ph.D. ⁽¹⁾	56	Director
Wei Ren ⁽²⁾⁽³⁾	44	Director
David Sidransky, M.D. ⁽²⁾⁽⁴⁾⁽⁵⁾	64	Director
Shaomeng Wang, Ph.D. ⁽⁴⁾	61	Director
Changqing Ye ⁽¹⁾⁽³⁾	54	Director
Debra Yu ⁽³⁾⁽²⁾	60	Director

(1) Member of the audit committee

(2) Member of the nomination committee

(3) Member of the remuneration committee

(4) Member of the research and development committee

(5) Lead Independent Non-Executive Director

Dajun Yang, M.D., Ph.D. is our co-founder and has served as our Chief Executive Officer since 2009 and as Chairman and a member of our board of directors since 2017. Prior to co-founding our Company, Dr. Yang co-founded Ascenta Therapeutics, Inc., where he was a Senior Vice President of Research and Preclinical Development between 2004 and 2008. Prior to that, Dr. Yang was a part-time professor and supervisor of doctoral students at the Cancer Center at Sun Yat-sen University from 2003 to 2006 and an Associate Professor of Biochemistry and Molecular Biology, an Associate Professor of Oncology and Senior Investigator at the Lombardi Cancer Center at Georgetown University from 1995 to 2001. Dr. Yang is also a co-founder of two national magazines in China, “Chinese Medical Students” and “Family Doctors.” Dr. Yang received his Bachelor’s in Medicine and his Master’s in Oncology from Sun Yat-sen University in China and his Ph.D. in Genetics from Michigan State University.

Yifan Zhai, M.D., Ph.D. has served as our Chief Medical Officer since July 2013. Dr. Zhai was the President of the Chinese Biopharmaceutical Association-USA from 2009 to 2010. From 2007 to 2010, Dr. Zhai served as Chief Scientific Officer of Celladon Corporation, a biotechnology company previously listed on Nasdaq until its merger with Eiger Biopharmaceuticals, Inc. Prior to that, she served as Executive Director of Anaborex (Shanghai) R&D Co., Ltd. from 2007 to 2008, as Chief Scientific Officer at Oncomax Acquisition Corp. from 2005 to 2007, as President of HealthQuest Inc. from 2003 to 2005, as Director of the Department of Pharmacology at Exelixis, Inc. (Nasdaq: EXEL) from 2001 to 2003, as a Senior Research Scientist at Bayer Pharmaceuticals Corp. from 1999 to 2001, and as a Scientist at Human Genome Sciences Inc. (acquired by GSK plc), from 1996 to 1999. Dr. Zhai was a Postdoctoral Fellow at the surgery branch of the National Cancer Institute from 1993 to 1996. Dr. Zhai received her M.D. from Sun Yat-sen University in China and her Ph.D. in Pharmacology and Toxicology from Michigan State University.

Veet Misra, Ph.D. has been our Chief Financial Officer since July 2025. Dr. Misra has more than 20 years of experience in investment banking. Prior to joining Ascentage Pharma, he was a Managing Director in the Healthcare Investment Banking group at Cantor Fitzgerald where he covered the biopharmaceutical sector. Before that, he worked in the life sciences investment banking groups at Houlihan Lokey and RBC Capital Markets. Over the course of his banking career, Dr. Misra advised on deals spanning equity, equity-linked, debt, and debt restructuring, as well as buy-side/sell-side M&A and corporate strategy, primarily focusing on the biotechnology sector. Dr. Misra earned a Ph.D. in Molecular Biology, with a focus on the oncology field, from the University of Toronto and an MBA in Finance & Strategy from the Schulich School of Business in Toronto.

Thomas J. Knapp, J.D. has served as our Senior Vice President, General Counsel since March 2019. He was previously our Senior Vice President of Legal Affairs from 2018 to March 2019. From 2018 to February 2019, he served as a consultant at SELLAS Life Sciences Group, Inc. (Nasdaq: SLS), which acquired Galena Biopharma, Inc. in a reverse merger. Prior to that, from 2015 to 2018, Mr. Knapp was the General Counsel and Corporate Secretary at Galena Biopharma, Inc., a biopharmaceutical company previously listed on Nasdaq. From 2010 to 2015, he was Executive Vice President, Chief Legal Officer and Corporate Secretary of Sucampo Pharmaceuticals, Inc., a biopharmaceutical company acquired by Mallinckrodt Pharmaceuticals. From 2009 to 2010, he was a consultant to NorthWestern Energy Corporation (NYSE: NWE) and Of Counsel at Exemplar Law Partners, LLC, where he advised clients on renewable energy and financing funding. From 2003 to 2008, he was Vice President, General Counsel and Corporate Secretary at NorthWestern Energy Corporation (NYSE: NWE). From 1996 to 1998 and 1999 to 2002, he was Of Counsel at Paul Hastings LLP and has also served as Assistant General Counsel of The Boeing Company (NYSE: BA) from 1998 to 1999. Mr. Knapp was appointed as the Assistant Attorney General of the State of Illinois in 1978. In addition, he was also a mediation panelist of the American Bar Association from 2015 to 2018. From 2017 to April 2019, Mr. Knapp served on the board of directors of Osiris Therapeutics, Inc., which was previously listed on Nasdaq (Nasdaq: OSIR) and subsequently acquired by Smith & Nephew plc (NYSE: SNN) in April 2019. Mr. Knapp received his Bachelor’s in Political Science and Business from the University of Illinois Urbana-Champaign and his Juris Doctor from the Loyola University of Law.

Jin Cao has been our Head of Finance, China (acting Principal Financial and Accounting Officer) since December 2020. Prior to joining our company, he was Deputy Director of Finance of Simcere Pharmaceutical from 2016 to 2020. Mr. Cao started his career in Huawei Technology South America Division and served as regional Chief Accountant, where he was in charge of a number of finance and control functions in various operations. Mr. Cao received a Bachelor of Literature from Nanjing University and is a Certified Public Accountant and Certified Tax Advisor in China and also has Legal Professional Qualification from the Ministry of Justice of China.

Non-employee directors

Marina S. Bozilenko has served as a member of our board of directors since November 2024. Since July 2021, Ms. Bozilenko has served as President, Chief Executive Officer & Director at Biothea Pharma, Inc. She currently serves as an independent director of Talphera, Inc. (Nasdaq: TLPH). Previously, Ms. Bozilenko served as a Strategic Advisor at William Blair & Co. LLC from January 2010 to February 2021. Prior to that, Ms. Bozilenko served as a Principal at Kidd & Co. LLC from 2008 to 2010, Senior Managing Director at Bear, Stearns & Co., Inc. from 2003 to 2008, Managing Director at Banc of America Securities LLC from 2000 to 2003 and MD & Senior MD-West Coast Healthcare Investment at Prudential Vector Healthcare Group from 1999 to 2000. Prior to that, Ms. Bozilenko was Managing Director at Vector Securities LLC and Managing Director & Head-West Coast at Vector Securities International, Inc. from 1998 to 1999. She has previously served as a director of Olema Pharmaceuticals, Inc. (Nasdaq: OLMA) from 2010 to 2020 and as a director of SynAct Pharma AB (Nasdaq Stockholm: SYNACT) from April 2021 to February 2024. Ms. Bozilenko received her Bachelor's degree in Biochemistry and her Master's degree in Social Sciences from The University of Chicago.

Marc E. Lippman, M.D. has served as a member of our board of directors since January 2025. Dr. Lippman has served as a professor of Oncology and Internal Medicine at Georgetown University Medical Center since 2018. Dr. Lippman previously served as the Kathleen and Stanley Glaser Professor of Medicine at the University of Miami Leonard M. Miller School of Medicine from 2017 to 2018 and as deputy director of Sylvester Comprehensive Cancer Center at the University of Miami from 2008 to 2017. He also previously served as the John G. Searle Professor and Chair of Internal Medicine at the University of Michigan, Ann Arbor. Prior to that, Dr. Lippman was the Head of the Medical Breast Cancer Section, Medicine Branch, at the National Institutes of Health and was a Senior Investigator at the National Cancer Institute. Dr. Lippman currently serves on the board of directors of Radiance Biopharma, Inc., a biotech start-up, and previously served on the board of directors of Seagen Inc., a public company which was acquired by Pfizer Inc. (NYSE: PFE). Dr. Lippman has published over 500 peer-reviewed articles and is a recipient of the First American Cancer Society Lectureship and Prize at the American Society of Clinical Oncology Meeting, the American Association for Cancer Research Rosenthal Award and the Brinker Award for Basic Science of the Komen Foundation. Dr. Lippman is a member of the Association of American Physicians, the American Society for Clinical Investigation, the American Society of Biological Chemists, the American Association for Cancer Research and the American Society of Clinical Oncology. Dr. Lippman received his Bachelor's in Chemistry from Cornell University, and his M.D. from Yale Medical School.

Simon Dazhong Lu, Ph.D. has served as a member of our board of directors since 2018. Since 2009, Dr. Lu has served as the Managing Director and Partner of SDIC Fund Management Company Ltd., a PRC-based private equity fund manager. From 2008 and 2009, Dr. Lu worked at CEL Partners, a private equity firm that focuses on buy-outs, acquisitions and mergers. From 2002 to 2007, Dr. Lu served as the Investment Manager and Partner of Shanghai Newmargin Ventures, a venture capital management company based in the PRC. Prior to that, Dr. Lu worked in a number of financial institutions, including China International Capital Corporation Limited, an investment bank based in the PRC from 2001 to 2002. Dr. Lu received his Bachelor's in Economics from Nankai University in China. He received his Master's in Business Administration from McGill University in Canada, and his Ph.D. in Economics from Nankai University in China.

Wei Ren has served as a member of our board of directors since June 2019. Mr. Ren has been a lawyer at Jingtian & Gongcheng, a law firm in the PRC, since 2003, where he has served as a Partner since 2009. Mr. Ren received his Bachelor's in Law and his Bachelor's in Economics from Peking University in China.

David Sidransky, M.D. has served as a member of our board of directors since March 2021 and our lead independent director since December 2025. Dr. Sidransky currently serves as the director of the Head and Neck Cancer Research Division, Professor of Otolaryngology— Head and Neck Surgery, Professor of Cellular and Molecular Medicine, and Professor of Urology and Genetics at The Johns Hopkins University. Dr. Sidransky also currently serves as Professor of Oncology at the Johns Hopkins Oncology Center. Dr. Sidransky completed a fellowship in Oncology at The Johns Hopkins University and Hospital in 1992 and was appointed to its faculty that year. Dr. Sidransky is a member of the American Association of Cancer Research and the American Society of Clinical Oncology and has received certifications from the American Board of Internal Medicine and the American Board of Medical Oncology. In addition, Dr. Sidransky currently sits on the National Board of Scientific Advisors of the National Cancer Institute. Dr. Sidransky is a founder of Champions Oncology, Inc. (Nasdaq: CSBR) and serves as a director of Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD), Orgenesis Inc. (Nasdaq: ORGS) and Ayala Pharmaceuticals, Inc. (OTCQX: ADXS). He is also Chairman of the Medical Advisory Board of the Flight Attendants Medical Research Foundation and the Adenocystic Carcinoma Research. Dr. Sidransky has received numerous honors, such as the Israel Cancer Research Fund Osseman Award, the AACR- Richard and Hinda Rosenthal Foundation Award, the Toby Comet Award Bar Ilan University and the AACR Team Award Theme Circulating DNA. Dr. Sidransky received his Bachelor's in Chemistry from Brandeis University and his M.D. from the Baylor College of Medicine.

Shaomeng Wang, Ph.D. is our co-founder and has served as a member of our board of directors since 2017 and as chairman of our Scientific Advisory Board since 2010. Dr. Wang joined the University of Michigan in 2001 as a tenured faculty and is currently a Warner-Lambert/Parke Davis Professor in Medicine at the University of Michigan, Ann Arbor, where he also serves as director of the Michigan Center for Therapeutic Innovation. Prior to that, he served as an Assistant Professor from 1996 to 2000 and as Associate Professor from 2000 to 2001 at the Georgetown University Medical Center. Dr. Wang received his Bachelor's in Chemistry from Peking University in China, his Ph.D. in Chemistry from Case Western Reserve University and did his postdoctoral training at the National Cancer Institute, National Institutes of Health. Dr. Wang served as the Editor-in- Chief for the Journal of Medicinal Chemistry, American Chemical Society from 2011 to 2020.

Changqing Ye has served as a member of our board of directors since June 2019. From 2011 to 2015, Mr. Ye served as the Managing Director, Chief Financial Officer and a member of the investment committee at CITIC Private Equity Funds, a PRC-based private equity fund. Prior to that, from 1993 to 2011, Mr. Ye worked at PricewaterhouseCoopers Zhong Tian LLP, most recently as the Partner and Service Line Leader of the firm's advisory services and transaction services at the firm's Shanghai Office. Mr. Ye currently serves as an independent non-executive director of Baozun Inc. (Nasdaq: BZUN), Niu Technologies (Nasdaq: NIU), Jinxin Fertility Group Limited (HKEX Stock Code: 1951) and Hygeia Healthcare Holdings Co., Limited (HKEX Stock Code: 6078). He previously served as an independent non-executive director of Luzhou Bank Co., Ltd. (formerly known as Luzhou City Commercial Bank Co., Ltd. (HKEX Stock Code: 1983)), VNET Group, Inc. (Nasdaq: VNET) and NWTN Inc. (Nasdaq: NWTN). Mr. Ye received his Bachelor's in Journalism from Huazhong University of Science and Technology in China, and his Master's in Business Administration from the University of Warwick in the United Kingdom. Mr. Ye has been a Certified Public Accountant of the PRC since 1994.

Debra Yu has served as a member of our board of directors since November 2024. Ms. Yu has served as Chief Operating Officer and Partner at Panacea Venture since March 2023. She currently serves as a director of MeiraGTx Holdings PLC (Nasdaq: MGTx) and JW (Cayman) Therapeutics Co Ltd (HKEX Stock Code: 2126). She served as Chief Strategy Officer, Strategy and President at LianBio and in other positions from October 2019 until December 2022. She previously served as Managing Director and Head of Cross Border Healthcare Investment Banking at China Renaissance Securities (U.S.), a brokerage firm, from 2016 to 2019. From 2009 to 2016, she served as Managing Director of Labrador Advisors, LLC. Prior to that, she was Vice President, Strategy at WuXi Apptec between 2008 and 2009, where she helped to architect and co-lead Pfizer's venture capital team, and a member of Pfizer's Worldwide Business Development organization between 2005 and 2008. Prior to that, she was a Bay Area venture investor for several years, serving as General Partner of Delphi Ventures from 1995 to 1998 and Managing Director of Bay City Capital from 1998 to 2001. She has also held positions at McKinsey & Co. in New York and London between 1992 and 1995, and she began her career as an analyst at Morgan Stanley from 1987 to 1988. She received her Bachelor's degree in Molecular Biology from Princeton University and her M.D. from Harvard Medical School.

Family relationships

Dr. Yang and Dr. Zhai are married.

Arrangements for election of directors and members of management

There are no contracts or other arrangements pursuant to which our executive officers or Directors have been or must be selected.

B. Compensation

Executive officer and director compensation

Compensation of chief executive officer

The following table sets out the compensation awarded to Dr. Dajun Yang, our Chairman, Chief Executive Officer and Director, in the fiscal year ended December 31, 2025

Name	Fees (RMB)	Fees (USD)	Salaries, allowances and benefits in kind (RMB)	Salaries, allowances and benefits in kind (USD)	Share option expenses (RMB)	Share option expenses (USD)	Pension scheme contributions(1) (RMB)	Pension scheme contributions(1) (USD)	Total (RMB)	Total (USD)
Dr. Dajun Yang	—	—	40,938,595	5,854,141	617,219	88,261	219,454	31,381	41,775,267	5,973,783

- (1) Our PRC subsidiaries are required by law to make contributions equal to certain percentages of each employee's salary for, among other things, his or her pension insurance.
- (2) A portion of Dr. Dajun Yang's "Salaries, allowances and benefits" includes a bonus payment of RMB17,106,000 (USD 2,394,847) which represent the payment for the cancelled RSUs granted in 2023 and 2024 as his bonus for those years.

Compensation of senior management

The following table sets out the aggregate compensation awarded to Dr. Dajun Yang, Dr. Yifan Zhai, and Veet Misra, as a group, in the fiscal year ended December 31, 2025.

Short term employee benefits(1) (RMB)	Short term employee benefits(1) (USD)	Equity-settled shares-based payment expenses(2) (RMB)	Equity-settled shares-based payment expenses(2) (USD)	Post- employment benefits(3) (RMB)	Post- employment benefits(3) (USD)	Total (RMB)	Total (USD)
55,099,657	7,879,146	742,520	106,179	711,144	101,692	56,553,321	8,087,017

- (1) Relates to compensation and bonuses to be settled within 12 months of employees rendering services, recognized as expenses when incurred.
- (2) Relates to awards granted prior to 2025 and settled during 2025, which are disclosed here consistent with the Company's customary practice.
- (3) Relates to amounts contributed by (1) our PRC subsidiaries to statutory PRC post-employment programs, or (2) our U.S. subsidiary to its defined contribution 401(k) savings plan, as applicable.

Compensation of directors

The following table sets out the compensation awarded to our non-executive directors in the fiscal year ended December 31, 2025.

Name	Fees (RMB)	Fees (USD)	Allowances and Benefits in Kind(1) (RMB)	Allowances and Benefits in Kind(1) (USD)	Share Option Expenses (RMB)	Share Option Expenses (USD)	RSU Expense(2) (RMB)	RSU Expense(2) (USD)	Pension Scheme Contributions (RMB)	Pension Scheme Contributions (USD)	Total (RMB)	Total (USD)
<i>Non-Executive Directors</i>												
Dr. Shaomeng Wang	428,573	61,285	1,181,254	168,917	—	—	294,571	42,123	—	—	1,904,398	272,325
Dr. Simon Dazhong Lu	—	—	—	—	—	—	294,571	42,123	—	—	294,571	42,123
<i>Independent Non-Executive Directors</i>												
Mr. Changqing Ye	428,573	61,285	—	—	—	—	307,521	43,975	—	—	736,094	105,260
Mr. Wei Ren	428,573	61,285	—	—	—	—	307,521	43,975	—	—	736,094	105,260
Dr. David Sidransky	428,573	61,285	—	—	—	—	307,521	43,975	—	—	736,094	105,260
Marc E. Lippman	428,573	61,285	—	—	—	—	294,571	42,123	—	—	723,144	103,408
Marina Bozilenko⁽⁴⁾	428,573	61,285	—	—	—	—	294,571	42,123	—	—	723,144	103,408
Debra Yu⁽⁵⁾	428,573	61,285	—	—	—	—	294,571	42,123	—	—	723,144	103,408

(1) Relates to payments to be settled within 12 months of Directors rendering services, recognized as expenses when incurred.

(2) Relates to awards granted prior to 2025 and settled during 2025, which are disclosed here consistent with the Company's customary practice.

Equity incentive plans

2018 restricted share unit scheme

Our 2018 RSU Plan was originally adopted in July 2018.

Our 2018 RSU Plan allows us to provide RSUs to existing or incoming employees, directors or officers of ours, our subsidiaries and companies whose financial results have been consolidated and accounted as subsidiaries of Ascentage Pharma by virtue of the contractual arrangements.

Under our 2018 RSU Plan, we may issue RSUs covering a maximum of 5,274,657 ordinary shares. As of December 31, 2025, there were 6,294 RSUs covering ordinary shares outstanding under our 2018 RSU Plan.

Purpose of the 2018 RSU plan. The purpose of our 2018 RSU Plan was to incentivize the existing and incoming directors, senior management and employees for their contribution to our Company and to attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of our Company by providing them with the opportunity to own equity interests in our Company.

Plan administration. Our 2018 RSU Plan is administered by our board of Directors or a duly authorized committee of our board of directors, or the Administrator. The decision of the Administrator as to all matters relating to our 2018 RSU Plan or its interpretation or effect is final and binding.

We appointed a trustee to assist with the administration and vesting of RSUs granted pursuant to our 2018 RSU Plan. All ordinary shares underlying the RSUs granted and to be granted under the RSU 2018 Plan are or were transferred, allotted or issued to the trustee.

Eligibility. Existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of our Company were eligible to receive grants of RSUs.

Restricted share units. Each RSU represents one underlying ordinary share, and represent a conditional right granted to any participant to obtain the corresponding economic value of the underlying ordinary shares, less any tax, stamp duty and other charges applicable, as determined by the Administrator in its absolute discretion.

Subject to the provisions of our 2018 RSU Plan, the Administrator determines the terms and conditions of RSUs, including the vesting criteria and the timing of payment. Each award of RSUs is evidenced by a grant letter setting forth the material terms of such award.

Within a reasonable time after the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, the Administrator will send a vesting notice to each relevant participant confirming the extent to which the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, and the number of ordinary shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those ordinary shares) involved. RSUs that are vested may be exercised (in whole or in part) by serving an exercise notice in writing on the trustee and copied to the Company on the terms set forth in the letter of grant, vesting notice or other applicable agreement between the Company and a participant. Unvested RSUs terminate on a participant's termination of employment or service or upon an attempt to transfer or encumber the RSUs in an impermissible manner under the terms of our 2018 RSU Plan. Additionally, RSUs will be forfeited if a participant breaches certain restrictive covenants set forth in our 2018 RSU Plan.

The Administrator may at its discretion cancel any RSU that has not vested or lapsed, provided that the Company must either (1) cash out the RSUs, (2) grant a replacement award of equivalent value, or (3) make other arrangements to compensate the applicable participant.

Non-transferability of Awards. The RSUs granted under our 2018 RSU Plan are personal to each participant and are not assignable. Participants are prohibited from selling, transferring, assigning, charging, mortgaging, encumbering, hedging or creating any interest in favor of any other person over or in relation to any property held by the trustee on trust for the participants, the RSUs, or any interest or benefits therein.

Certain adjustments. In the event of any capitalization issue, rights issue, consolidation, sub-division or reduction of the share capital of the Company, the Administrator may make such equitable adjustments, designed to protect participants' interests, to the number of ordinary shares underlying the outstanding RSUs or to the amount of the equivalent value, as it may deem appropriate at its absolute discretion.

Corporate transactions. If a general offer to acquire the ordinary shares (whether by takeover offer, merger, or otherwise in a like manner) is made to all of the shareholders of the Company (or shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in concert with the offeror) and the general offer to acquire the ordinary shares is approved and the offer becomes or is declared unconditional in all respects, a participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

If a compromise or arrangement between the Company and its shareholders or creditors is proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies and a notice is given by the Company to its shareholders to convene a general meeting to consider and if thought fit approve such compromise or arrangement and such shareholders' approval is obtained, a participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

If, prior to the termination of our 2018 RSU Plan, an effective resolution is passed for the voluntary winding-up of the Company (other than for the purposes of a reconstruction, amalgamation or scheme of arrangement), all outstanding RSUs shall be treated as having vested immediately. No ordinary shares will be transferred, and no cash alternative will be paid, to the participant, but the participant will be entitled to receive out of the assets available in liquidation on an equal basis with the Company's shareholders such sum as they would have received in respect of the RSUs.

Amendment and termination. Our board of directors may, at any time, terminate or amend our 2018 RSU Plan in any respect, provided that consent is needed for material amendments to the 2018 RSU Plan or amendment of awards which are materially adverse to a participant.

2021 Restricted Share Unit Scheme

Our 2021 Restricted Share Unit Scheme, or 2021 RSU Plan, was adopted in February 2021 and amended in April 2025.

Our 2021 RSU Plan allows us to provide RSUs to existing or incoming employees, directors or officers of our Company or any member of our group or a service provider (as defined in the 2021 RSU Plan).

Under our 2021 RSU Plan, we may issue RSUs covering a maximum of 3,133,526 ordinary shares. As of December 31, 2025, RSUs covering 443,127 ordinary shares were outstanding under our 2021 RSU Plan.

Purpose of the 2021 RSU plan. The purpose of our 2021 RSU Plan was to incentivize the existing and incoming directors, senior management and employees for their contribution to our Company and to attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of our Company by providing them with the opportunity to own equity interests in the Company.

Plan administration. Our 2021 RSU Plan is administered by the plan Administrator (which is similarly defined under the 2021 RSU Plan as under our 2018 RSU Plan). The decision of the Administrator as to all matters relating to our 2021 RSU Plan or its interpretation or effect is final and binding.

We appointed a trustee to assist with the administration and vesting of RSUs granted pursuant to our 2021 RSU Plan. All ordinary shares underlying the RSUs granted and to be granted under the RSU 2021 Plan are or were transferred, allotted or issued to the trustee.

Eligibility. Existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of our group or a service provider (as defined in the 2021 RSU Plan) were eligible to receive grants of RSUs.

Restricted share units. Each RSU represents one underlying ordinary share, and represent a conditional right granted to any participant to obtain the corresponding economic value of the underlying ordinary shares, less any tax, stamp duty and other charges applicable, as determined by the Administrator in its absolute discretion. Subject to the provisions of our 2021 RSU Plan, the Administrator determines the terms and conditions of RSUs, including the vesting criteria and the timing of payment. Each award of RSUs is evidenced by a grant letter setting forth the material terms of such award.

Within a reasonable time after the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, the Administrator will send a vesting notice to each relevant participant confirming the extent to which the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, and the number of ordinary shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-script distributions in respect of those ordinary shares) involved. Unvested RSUs terminate on a participant's termination of employment or service or upon an attempt to transfer or encumber the RSUs in an impermissible manner under the terms of our 2021 RSU Plan, provided that the Administrator may choose to accelerate the vesting of unvested RSUs within 30 days following a participant's termination of service due to death. Additionally, RSUs will be forfeited if a participant breaches certain restrictive covenants set forth in our 2021 RSU Plan.

The Administrator may at its discretion cancel any RSU that has not vested or lapsed, provided that the Company must either (1) cash out the RSUs, (2) grant a replacement award of equivalent value, or (3) make other arrangements to compensate the applicable participant.

Non-transferability of Awards. The RSUs granted under our 2021 RSU Plan are personal to each participant and are not assignable. Participants are prohibited from selling, transferring, assigning, charging, mortgaging, encumbering, hedging or creating any interest in favor of any other person over or in relation to any property held by the trustee on trust for the participants, the RSUs, or any interest or benefits therein.

Certain adjustments. In the event of any capitalization issue, rights issue, consolidation, sub-division or reduction of the share capital of the Company, the Administrator may make such equitable adjustments, designed to protect participants' interests, to the number of ordinary shares underlying the outstanding RSUs or to the amount of the equivalent value, as it may deem appropriate in accordance with the guidance of the Hong Kong Stock Exchange issued from time to time and as the auditors or the independent financial adviser of the Company retained for such purpose shall certify in writing to the Board to be in their opinion fair and reasonable.

Corporate transactions. If a general offer to acquire the ordinary shares (whether by takeover offer, merger, or otherwise in a like manner) is made to all of the shareholders of the Company (or shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in concert with the offeror) and the general offer to acquire the ordinary shares is approved and the offer becomes or is declared unconditional in all respects, an employee participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

If a compromise or arrangement between the Company and its shareholders or creditors is proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies and a notice is given by the Company to its shareholders to convene a general meeting to consider and if thought fit approve such compromise or arrangement and such shareholders' approval is obtained, an employee participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

If, prior to the termination of our 2021 RSU Plan, an effective resolution is passed for the voluntary winding-up of the Company (other than for the purposes of a reconstruction, amalgamation or scheme of arrangement), all outstanding RSUs of an employee participant shall be treated as having vested immediately. No ordinary shares will be transferred, and no cash alternative will be paid, to the participant, but the participant will be entitled to receive out of the assets available in liquidation on an equal basis with the Company's shareholders such sum as they would have received in respect of the RSUs.

Amendment and termination. Subject to the 2021 RSU Plan and the compliance with the Hong Kong Listing Rules, save for any alterations to the 2021 RSU Plan which are of a material nature of any alterations to the provisions relating to the matters set out in Rule 17.03 of the Hong Kong Listing Rule to the advantage of the participants must be approved by the shareholders in general meeting, the Board may amend any of the provisions of the 2021 RSU Plan (including without limitation to amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of the 2021 RSU Plan, which are not found in Chapter 17 of the Hong Kong Listing Rules) at any time. Subject to compliance with the Hong Kong Listing Rules, any change to the terms of the awards granted to a participant must be approved by our board of directors, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, as the case may be, if the initial grant of the awards was approved by our board of directors, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, correspondingly. This requirement does not apply to the alterations that take effect automatically under the existing terms of the 2021 RSU Plan. The amended terms of the 2021 RSU Plan must still comply with the applicable provisions of the Hong Kong Listing Rules. Our board of directors may terminate the 2021 RSU Plan at any time before the expiry of the relevant scheme period.

2022 restricted share unit scheme

Our 2022 Restricted Share Unit Scheme, or 2022 RSU Plan, was adopted in June 2022 and amended in May 2025.

Our 2022 RSU Plan allows us to provide RSUs to existing or incoming employees, directors or officers of our Company or any member of our group or a service provider (as defined in the 2022 RSU Plan).

Under our 2022 RSU Plan, we may issue RSUs covering a maximum of the amount equal to 2% of the ordinary shares in issue as of the date of adoption, or 11,072,695 ordinary shares. As of December 31, 2025, RSUs covering 5,582,518 ordinary shares were outstanding under our 2022 RSU Plan.

Purpose of the 2022 RSU plan. The purpose of our 2022 RSU Plan was to incentivize the existing and incoming directors, senior management and employees for their contribution to our Company and to attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of our Company by providing them with the opportunity to own equity interests in the Company.

Plan administration. Our 2022 RSU Plan is administered by the plan Administrator (which is similarly defined under the 2022 RSU Plan as under our 2018 RSU Plan). The decision of the Administrator as to all matters relating to our 2022 RSU Plan or its interpretation or effect is final and binding.

We appointed a trustee to assist with the administration and vesting of RSUs granted pursuant to our 2022 RSU Plan. All ordinary shares underlying the RSUs granted and to be granted under the RSU 2022 Plan are or were transferred, allotted or issued to the trustee.

Eligibility. Existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of our group or a service provider (as defined in the 2022 RSU Plan) were eligible to receive grants of RSUs.

Restricted share units. Each RSU represents one underlying Share, and represent a conditional right granted to any participant to obtain the corresponding economic value of the underlying ordinary shares, less any tax, stamp duty and other charges applicable, as determined by the Administrator in its absolute discretion. Subject to the provisions of our 2022 RSU Plan, the Administrator determines the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. Each award of RSUs is evidenced by a grant letter setting forth the material terms of such award.

Within a reasonable time after the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, the Administrator will send a vesting notice to each relevant participant confirming the extent to which the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, and the number of ordinary shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those ordinary shares) involved. Unvested RSUs terminate on a participant's termination of employment or service or upon an attempt to transfer or encumber the RSUs in an impermissible manner under the terms of our 2022 RSU Plan, provided that unvested RSUs will remain outstanding for 3 months following termination of employment or service. Additionally, RSUs will be forfeited if a participant breaches certain restrictive covenants set forth in our 2022 RSU Plan and any shares or consideration previously transferred to a participant in respect of RSUs may be recoverable by the trustee in accordance with the terms of our 2022 RSU Plan.

The Administrator, in its sole discretion, may pay earned RSUs in the form of cash, in shares or in some combination thereof. The Administrator may at its discretion cancel any RSU that has not vested or lapsed, provided that the Company must either (1) cash out the RSUs, (2) grant a replacement award of equivalent value, or (3) make other arrangements to compensate the applicable participant.

Non-transferability of Awards. The RSUs granted under our 2022 RSU Plan are personal to each participant and are not assignable. Participants are prohibited from selling, transferring, assigning, charging, mortgaging, encumbering, hedging or creating any interest in favor of any other person over or in relation to any property held by the trustee on trust for the participants, the RSUs, or any interest or benefits therein.

Certain adjustments. In the event of any capitalization issue, rights issue, consolidation, sub-division or reduction of the share capital of the Company, the Administrator may make such equitable adjustments, designed to protect participants' interests, to the number of ordinary shares underlying the outstanding RSUs or to the amount of the equivalent value, as it may deem appropriate in accordance with the guidance of the Hong Kong Stock Exchange issued from time to time and as the auditors or the independent financial adviser of the Company retained for such purpose shall certify in writing to the Board to be in their opinion fair and reasonable.

Corporate transactions. If a general offer to acquire the ordinary shares (whether by takeover offer, merger, or otherwise in a like manner) is made to all of the shareholders of the Company (or shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in concert with the offeror) and the general offer to acquire the ordinary shares is approved and the offer becomes or is declared unconditional in all respects, a participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

If a compromise or arrangement between the Company and its shareholders or creditors is proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies and a notice is given by the Company to its shareholders to convene a general meeting to consider and if thought fit approve such compromise or arrangement and such shareholders' approval is obtained, an employee participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

If, prior to the termination of our 2022 RSU Plan, an effective resolution is passed for the voluntary winding-up of the Company (other than for the purposes of a reconstruction, amalgamation or scheme of arrangement), all outstanding RSUs of an employee participant shall be treated as having vested immediately. No ordinary shares will be transferred, and no cash alternative will be paid, to the participant, but the participant will be entitled to receive out of the assets available in liquidation on an equal basis with the Company's shareholders such sum as they would have received in respect of the RSUs.

Amendment and termination. Subject to the 2022 RSU Plan and the compliance with the Hong Kong Listing Rules, save for any alterations to the 2022 RSU Plan which are of a material nature of any alterations to the provisions relating to the matters set out in Rule 17.03 of the Hong Kong Listing Rule to the advantage of the participants must be approved by the shareholders in general meeting, the Board may amend any of the provisions of the 2022 RSU Plan (including without limitation to amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of the 2022 RSU Plan, which are not found in Chapter 17 of the Hong Kong Listing Rules) at any time. Subject to compliance with the Hong Kong Listing Rules, any change to the terms of the awards granted to a participant must be approved by our board of directors, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, as the case may be, if the initial grant of the awards was approved by our board of directors, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, correspondingly. This requirement does not apply to the alterations that take effect automatically under the existing terms of the 2022 RSU Plan. The amended terms of the 2022 RSU Plan must still comply with the applicable provisions of the Hong Kong Listing Rules. Our board of directors may terminate the 2022 RSU Plan at any time before the expiry of the relevant scheme period.

Pre-IPO share option scheme

Our Pre-IPO Share Option Scheme, or Pre-IPO Option Plan, was adopted in July 2018.

Our Pre-IPO Option Plan allows us to provide options to purchase ordinary shares, or Options, to substantial shareholders, existing or incoming employees, directors or officers, or any other service providers of our Company. Our Pre-IPO Option Plan was terminated but continues to govern the terms and conditions of the outstanding awards previously granted under our Pre-IPO Option Plan.

As of December 31, 2025, there were no options covering ordinary shares outstanding under our Pre-IPO Option Plan.

Purpose of the Pre-IPO Option Plan. The purpose of our Pre-IPO Option Plan was to reward participants who contributed or would contribute to our Company and to encourage participants to continue to work for our Company towards enhancing the value of the ordinary shares to benefit our Company and our shareholders as a whole.

Plan administration. Our Pre-IPO option plan is administered by the plan Administrator (which is similarly defined under the Pre-IPO Option Plan as under our 2018 RSU Plan). The decision of the Administrator as to all matters relating to our Pre-IPO Option Plan or its interpretation or effect is final and binding.

Eligibility. Substantial shareholders, existing or incoming employees, directors or officers, or any other service providers of our Company were eligible to receive grants of Options.

Options. Options can be granted under our Pre-IPO Option Plan. The exercise price of Options granted under our Pre-IPO Option Plan is HK\$0.01 per ordinary share. The Administrator determined the material terms of Options granted under our Pre-IPO Option Plan, which material terms were included in an offer letter issued to each participant under our Pre-IPO Option Plan, including (1) the minimum period for which the Options must be held before they can be exercised; (2) a performance target that must be reached before the Options can be exercised in whole or in part; and/or (3) any other terms, all of which may be imposed (or not imposed) either on a case-by-case basis or generally. Options are only considered granted in respect of timely accepted offer letters and on the terms set forth in such offer letters. Options must be exercised within the exercise period set forth in an applicable offer letter, which will not exceed 10 years from the date of such offer. Generally, subject to an applicable Option expiration date, a grantee may exercise the then exercisable portion of an Option for 3 months following termination of service, provided that (1) if a grantee dies before exercising an Option, his or her legal representative may exercise the Option within 12 months following the grantee's death, and (2) Options will automatically terminate in full if a grantee commits certain acts specified in Section 5(d) of our Pre-IPO Option Plan. Options will also expire upon the date of commencement of a winding up of the Company, upon the effectiveness of a compromise or arrangement, or, if a grantee is solely a substantial shareholder, on the date on which such grantee ceases to be a substantial shareholder.

Non-transferability of Options. Options are personal to the grantee and are not assignable or transferable. Options may not be sold, transferred, charged, mortgaged, or encumbered.

Certain adjustments. In the event of an alteration in the capital structure of the Company while any Options remain exercisable by way of capitalization of profits or reserves, bonus issue, rights issue, open offer, subdivision or consolidation of shares, or reduction of the share capital of the Company in accordance with legal requirements, corresponding adjustments (if any) will be made to the number of ordinary shares and exercise price of outstanding Options. Grantees will be notified in writing in the event of any such adjustments.

Corporate transactions. In the event of a general offer being made to all the shareholders, we will make best efforts to ensure that an appropriate offer is extended to all grantees. Upon such offer becoming or being declared unconditional, the grantee will be entitled to exercise the Option in full (to the extent not already lapsed or exercised) at any time within 1 month after the date on which the offer becomes or is declared unconditional.

In the event of a compromise or arrangement between the Company and the shareholders or its creditors being proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies pursuant to the Company's bylaws, the Company will give notice to all grantees and Options (to the extent not already lapsed or exercised) will become exercisable in whole or in part not later than 2 business days prior to the date of the general meeting directed to be convened by the court for the purposes of considering such compromise or arrangement, or the Suspension Date. With effect from the Suspension Date, the rights of all grantees to exercise their respective Options will be suspended and forfeited.

If a general meeting is convened to consider a voluntary resolution to wind-up the Company, the Company will provide notice to each grantee of entitlement to exercise all or any Options (to the extent not already lapsed or exercised) at any time not later than 2 business days prior to the proposed general meeting of the Company.

Amendment and termination. Specific provisions of our Pre-IPO Option Plan which relate to certain listing rules applicable to the Stock Exchange of Hong Kong Limited cannot be altered to the advantage of participants, and changes to the authority of the Administrator may not be made without the prior approval of our shareholders. Any alterations to the terms and conditions of our Pre-IPO Option Plan which are of a material nature, or any change to the terms of Options granted, must also, to be effective, be approved by our shareholders, except where the alterations take effect automatically under the existing terms of our Pre-IPO Option Plan. As noted above, our Pre-IPO Option Plan was terminated, and we will not grant any additional awards under our Pre-IPO Option Plan.

Post-IPO share option scheme

Our Post-IPO Share Option Scheme, or Post-IPO Option Plan, was adopted in September 2019 and amended in May 2025.

Our Post-IPO Option Plan allows us to provide Options to (a) any executive director of, manager of, or other employee holding an executive, managerial, supervisory or similar position in any member of our Company, any full-time or part-time employee, or a person for the time being seconded to work full-time or part-time for any member of our Company; (b) a director or proposed director (including an independent non-executive director) of any member of our Company; and (c) a service provider (as defined in the Post-IPO Share Option Scheme), or Eligible Persons.

Subject to adjustment, the maximum aggregate number of ordinary shares which may be issued subject to options under our Post-IPO Option Plan is 14,907,464 ordinary shares.

As of December 31, 2025, there were no options covering ordinary shares outstanding under our Post-IPO Option Plan.

Purpose of the Post-IPO option plan. The purpose of our Post-IPO Option Plan is to enable the Company to grant Options to Eligible Persons as incentives or rewards for their contribution or potential contribution to our Company and to provide the Eligible Persons an opportunity to have a personal stake in the Company with the view to motivate the Eligible Persons to optimize their performance efficiency for the benefit of our Company, attract and retain or otherwise maintain ongoing business relationship with the Eligible Persons whose contributions are or will be beneficial to the long-term growth of our Company, and/or for such purposes as the Administrator (which is similarly defined under the Post-IPO Option Plan as under our 2018 RSU Plan) shall determine.

Plan administration. Our Post-IPO Option Plan is administered by the plan Administrator. The decision of the Administrator as to all matters relating to our Post-IPO Option Plan or its interpretation or effect is final and binding. Notwithstanding the foregoing, subject to the Post-IPO Option Plan, if the Board determines to make an Offer to a substantial shareholder or an independent non-executive Director (or any of their respective associates) and that grant would result in the Shares issued and to be issued upon exercise of all options and awards already granted and to be granted (including options and awards exercised, cancelled and outstanding but excluding any options and awards lapsed in accordance with the terms of their respective schemes) to such person under this Scheme and the other schemes in the 12-month period up to and including the Offer Date representing in aggregate over 0.1 per cent, or such other percentage as may be from time to time provided under the Listing Rules, of the Shares in issue (excluding treasury Shares) on the Offer Date such grant shall be subject to, in addition to the approval of the independent non-executive Directors as referred to under the Post-IPO Option Plan, the issue of a circular by the Company to the Shareholders and the approval of the Shareholders in general meeting by way of a poll convened and held in accordance with the Articles at which the Grantee, his associates and all core connected persons of the Company shall abstain from voting in favor of the resolution concerning the grant of such Options at the general meeting, and/or such other requirements prescribed under the Hong Kong Listing Rules from time to time.

Eligibility. Eligible Persons (which consist of (a) any executive director of, manager of, or other employee holding an executive, managerial, supervisory or similar position in any member of our Company, any full-time or part-time employee, or a person for the time being seconded to work full-time or part-time for any member of our Company; (b) a director or proposed director (including an independent non-executive director) of any member of our Company; and (c) a service provider (as defined in the Post-IPO Share Option Scheme) are eligible to receive grants of Options under our Post-IPO Option Plan.

Options. Options can be granted under our Post-IPO Option Plan. The exercise price of Options granted under our Post-IPO Option Plan is determined by the Administrator but generally will not be less than the highest of the closing price of the Shares as stated in the daily quotation sheets of the Hong Kong Stock Exchange on the Offer Date, and the average of the closing price of the Shares as stated in the daily quotation sheets of the Stock Exchange for the five Business Days immediately preceding the Offer Date.

The Administrator determines the material terms of Options granted under our Post-IPO Option Plan, which material terms are included in an offer letter issued to each participant under our Post-IPO Option Plan, including the number of ordinary shares subject to an Option, the applicable exercise price, the vesting schedule, expiration date and the method of acceptance. Options must be exercised within the exercise period set forth in an applicable offer letter, which will not exceed 10 years from the date of such offer.

Generally, subject to an applicable Option expiration date, a grantee may exercise the then exercisable portion of an Option for 3 months following termination of service, provided that (1) if a grantee dies before exercising an Option, his or her legal representative may exercise the Option within 12 months following the grantee's death, and (2) Options will automatically terminate in full if a grantee commits certain acts specified in Section 8(d) of our Post-IPO Option Plan. Options will also expire upon the date of commencement of a winding up of the Company, upon the effectiveness of a compromise or arrangement, or, if a grantee is solely a substantial shareholder, on the date on which such grantee ceases to be a substantial shareholder. Additionally the Administrator may cancel Options if a grantee breaches the transferability provisions of our Post-IPO Option Plan or other terms or conditions of the grant of an Option, or if a grantee engages in conduct that is detrimental or prejudicial to the interests of the Company or its subsidiaries, as determined by the Administrator in its discretion.

Non-transferability of Options. Options are personal to the grantee and are not assignable or transferable. Options may not be sold, transferred, charged, mortgaged, or encumbered.

Certain adjustments. In the event of any capitalization issue, rights issue, sub-division or consolidation of shares or reduction of capital of the Company in accordance with applicable laws and regulatory requirements, such corresponding alterations (if any) shall be made (except on an issue of securities of the Company as consideration in a transaction which shall not be regarded as a circumstance requiring alteration or adjustment) in the number of ordinary shares subject to any outstanding Options and the Exercise Price of outstanding Options. The Company will notify affected participants of any such adjustments.

Corporate transactions. In the event of a general offer being made to all the shareholders, we will make best efforts to ensure that an appropriate offer is extended to all grantees. Upon such offer becoming or being declared unconditional, the employee participant will be entitled to exercise the Option in full (to the extent not already lapsed or exercised) at any time within 1 month after the date on which the offer becomes or is declared unconditional.

In the event of a compromise or arrangement between the Company and the shareholders or its creditors being proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies pursuant to the Company's bylaws, the Company will give notice to all grantees and Options (to the extent not already lapsed or exercised) granted to an employee participant will become exercisable in whole or in part not later than 2 business days prior to the date of the general meeting directed to be convened by the court for the purposes of considering such compromise or arrangement, or the Post-IPO Suspension Date. With effect from the Post-IPO Suspension Date, the rights of all grantees to exercise their respective Options will be suspended and forfeited.

If a general meeting is convened to consider a voluntary resolution to wind-up the Company, the Company will provide notice to each employee participant of entitlement to exercise all or any Options (to the extent not already lapsed or exercised) at any time not later than 2 business days prior to the proposed general meeting of the Company.

Amendment and termination. Subject to our Post-IPO Option Plan, and the compliance with the Hong Kong Listing Rules, save for any alternations to our Post-IPO Option Plan which are of a material natural of any alterations to the provisions relating to the matters set out in Rule 17.03 of the Hong Kong Listing Rules to the advantage of the participants must be approved by the Shareholders in general meeting, the Board may amend any of the provisions of our Post-IPO Option Plan (including without limitation to amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of our Post-IPO Option Plan, which are not found in Chapter 17 of the Hong Kong Listing Rules) at any time. Subject to compliance with the Hong Kong Listing Rules, any change to the terms of the Options granted to a participant must be approved by our board of directors, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, as the case may be, if the initial grant of the Options was approved by our board of directors, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, correspondingly. This requirement does not apply to the alterations take effect automatically under the existing terms of our Post-IPO Option Plan. The amended terms of our Post-IPO Option Plan must still comply with the applicable provisions of the Hong Kong Listing Rules.

The following table summarizes, as of April 20, 2026, the number of ordinary shares underlying outstanding options and RSUs that we have granted to our directors and executive officers under our equity incentive plans.

Name	Ordinary Shares Underlying Outstanding Awards	Exercise Price (US\$/Share)	Date of Grant	Date of Expiration
Executive Officers				
Dajun Yang, M.D., Ph.D.	46,972	—	19-May-23	N/A
Yifan Zhai, M.D., Ph.D.	126,000	—	19-May-23	N/A
	100,000	—	23-Jun-22	N/A
Veet Misra, Ph.D.	18,584	—		N/A
Non-Employee Directors				
Simon Dazhong Lu, Ph.D.	41,457	\$ 0.013	August 15, 2018	N/A
	10,472	—	26-Nov-25	N/A
Wei Ren	8,964	—	23-Jul-21	N/A
	10,990	—	26-Nov-25	N/A
David Sidransky, M.D.	10,641	—	17-May-21	N/A
	10,990	—	26-Nov-25	N/A
Changqing Ye	8,964	—	23-Jul-21	N/A
	10,990	—	26-Nov-25	N/A
Debra Yu, M.D.	10,472	—	26-Nov-25	N/A
Marina S. Bozilenko	10,472	—	26-Nov-25	N/A
Marc E. Lippman, M.D.	10,472	—	26-Nov-25	N/A
Shaomeng Wang, Ph.D.	10,472	—	26-Nov-25	N/A
All directors and executive officers as a group	1,255,070	—	—	—

Employment agreements and indemnification agreements

Dajun Yang labor contract

Dr. Yang's services in China are governed by a Labor Contract with Suzhou Ascentage Pharma Co., Ltd., or the Yang Labor Contract. The Yang Labor Contract has a term of five years, ending July 31, 2027, and provides for salary, and transportation, meal and communication subsidies. Other than in connection with a certain enumerated breaches or actions by Dr. Yang or by Suzhou Ascentage Pharma Co., Ltd., the Yang Labor Contract may only be terminated in accordance with the Labor Contract Law of the People's Republic of China. Dr. Yang is also subject to customary invention assignment and confidentiality provisions.

Yifan Zhai labor contract

Dr. Zhai's services in China are governed by a Labor Contract with Guangzhou Healthquest Pharma Co., Ltd., or the Zhai Labor Contract. The new Zhai Labor Contract has no fixed term and provides for salary, and transportation, meal and communication subsidies. Other than in connection with an enumerated breaches or actions by Dr. Zhai or by Guangzhou Healthquest Pharma Co., Ltd., the Zhai Labor Contract may only be terminated in accordance with the Labor Contract Law of the People's Republic of China. Dr. Zhai is also subject to customary invention assignment and confidentiality provisions.

Veet Misra offer letter

In June 2025, Ascentage Pharma Group Inc. entered into an employment letter agreement with Dr. Misra, our Chief Financial Officer, or the Misra Employment Letter. The Misra Employment Letter has no specific term and provides for at-will employment. In accordance with the Misra Employment Letter, Dr. Misra is currently eligible for an annual salary of USD\$525,000, and an annual bonus opportunity of 40% of his annual salary, and Dr. Misra is eligible for reimbursement of expenses incurred by him in connection with rendering services. Also in June 2025, Ascentage Pharma Group International awarded, subject to approval by the board of directors and compliance with the relevant laws and regulations (including the Rules Governing the Listing of Securities on The Stock Exchange Of Hong Kong Limited or Listing Rules), sign-on equity incentive RSUs with a value of \$1,500,000 and Options with a value of \$500,000 to vest in equal tranches over a four year period beginning with the first tranche vesting after the first anniversary of the date of employment. He was also awarded an annual performance incentive RSUs with a fair value of \$600,000 and Options with a fair value of \$600,000 each of which vest based on the successful attainment of specific performance measures. Both the sign-on incentive and annual performance incentive awards will be granted on such terms and provisions as are contained in the 2022 RSU Plan and the Post IPO Option Plan, respectively, Dr. Misra is also subject to customary invention assignment, confidentiality, and non-solicitation provisions.

Shaomeng Wang Service Agreement

In March 2022, Ascentage Pharma Group Corp Limited entered into an independent contractor service agreement with Dr. Wang, or the Wang Service Agreement. The Wang Service Agreement provides (1) for a term of three years ending March 1, 2025, which has been extended to March 1, 2027, (2) for annual compensation during the term in the amount of US\$165,375 per year, paid monthly, and (3) that Dr. Wang is eligible for reimbursement of expenses incurred by him in connection with rendering services to the Company, including related travel and living expenses. The Wang Service Agreement provides for customary invention assignment, confidentiality, and non-solicitation provisions.

Adoption of compensation recovery policy

On February 10, 2025, we adopted a compensation recovery policy in accordance with Rule 10D-1 promulgated under the Exchange Act and Nasdaq listing rules. A copy of our Compensation Recovery Policy is filed as Exhibit 97.1 to this Annual Report on Form 20-F.

C. Board Practices

Board of directors

Our board of directors currently consists of nine directors. A director is not required to hold any shares in our Company by way of qualification. A director may vote with respect to any contract or transaction, or proposed contract or transaction in which he or she is, whether directly or indirectly, materially interested provided such director, if his or her interest in such contract or transaction 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. Our directors may exercise all the powers of the company to borrow money, mortgage or charge its undertaking, property and assets (present or future) and uncalled capital or any part thereof, and issue debentures, debenture stock, bonds or other securities whether outright or as collateral security for any obligation of the company or of any third party. None of our non-employee directors has a service contract with us that provides for benefits upon termination of service.

Director independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have a majority of independent directors on our board of directors, except although our Audit Committee is required to consist solely of independent directors. Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a relationship with us that could interfere with such director's ability to exercise independent judgment in carrying out the responsibilities of a director. As a result of this review, our board of directors determined that Dr. Simon Dazhong Lu, Wei Ren, Dr. David Sidransky, Changqing Ye, Debra Yu, Marina Bozilenko, and Dr. Marc E. Lippman, representing seven of our nine directors, are "independent directors" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and corporate governance rules of Nasdaq. In making such determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director.

Board committees

We have established three committees under the board of directors: an audit committee, a remuneration committee, a nomination committee, and a research and development committee. We have adopted terms of reference for each of the four committees. Each committee's members and functions are described below.

Audit committee

The audit committee is comprised of three members, namely Changqing Ye, Dr. Simon Dazhong Lu and Marina S. Bozilenko, with Changqing Ye serving as chairman. Our board of directors has determined that each of Changqing Ye, Dr. Simon Dazhong Lu and Marina S. Bozilenko satisfies the "independence" requirements of Rule 10A-3 under the Exchange Act and the Nasdaq rules. We have determined that each of Changqing Ye, Dr. Simon Dazhong Lu and Marina S. Bozilenko qualifies as an "audit committee financial expert." The audit committee oversees our accounting and financial reporting processes and the audits of the financial statements of our Company. The audit committee is responsible for, among other things:

- appointing, compensating, retaining, evaluating and overseeing an independent registered public accounting firm to act as our independent auditor;
- ensuring the independence of our independent auditor;
- reviewing and discussing our internal controls and the integrity of our audited financial statements;
- discussing, with our management, procedures with respect to the presentation of our financial information and reviewing earnings press releases, earnings guidance provided to analysts and rating agencies and financial information provided to the public, analysts and ratings agencies;
- overseeing the design, implementation and performance of our internal audit function;
- overseeing our financial reporting system, risk management and internal control systems;
- performing our corporate governance functions;
- setting hiring policies with regard to the hiring of employees or former employees of our independent auditor and oversee compliance with such policies;
- reviewing, approving and monitoring related party transactions involving directors or executive officers, including developing and maintaining policies and procedures for reviewing, approving and/or ratifying such transactions;
- monitoring the Company's environmental, social and governance issues;
- overseeing procedures to address complaints received by us regarding accounting, internal accounting controls or auditing matters;
- reviewing and discussing with our management team and our independent auditor the adequacy and effectiveness of our legal, regulatory and ethical compliance programs and reports regarding compliance with applicable laws, regulations and internal compliance programs; and
- reviewing and discussing with management, including our internal audit function, if applicable, and our independent auditor guidelines and policies to identify, monitor, and address enterprise risks.

Remuneration committee

Our remuneration committee consists of Wei Ren, Changqing Ye and Debra Yu, with Wei Ren serving as chairman. Our board of directors has determined that each of Wei Ren, Changqing Ye and Debra Yu satisfies the “independence” requirements under the Nasdaq rules. The remuneration committee assists the board of directors in reviewing and approving the remuneration structure, including all forms of remuneration, relating to our directors and executive officers. The remuneration committee is responsible for, among other things:

- making recommendations to the board of directors on all the Company’s remuneration policy and structure for all executive officers’ remuneration and on the establishment of formal and transparent procedures for developing remuneration policy;
- reviewing and approving, annually, the corporate goals and objectives applicable to the compensation of our Chief Executive Officer, evaluating at least annually our Chief Executive Officer’s performance in light thereof, and consider factors related to the performance of the Company in approving the compensation level of our Chief Executive Officer;
- reviewing, at least annually, and approving or recommend for approval to the board members other than our Chief Executive Officer, our Chief Executive Officer’s (i) base salary, (ii) incentive bonus, including the specific goals and amount, (iii) equity compensation, (iv) any employment agreement, severance arrangement, transition or consulting agreement, retirement agreement or change of control protections and (v) any other benefits, compensation or similar arrangements, if any (including, without limitation, perquisites, pension rights, any benefits in kind, any compensation payments such as compensation payable for loss or termination of office or appointment, and any other form of compensation such as a signing bonus or payment of relocation costs), including any amendments to or terminations of any of the foregoing;
- reviewing, at least annually, and approving or recommending for approval to the board members other than our Chief Executive Officers items (i) through (v) above for the other executive officers, including any prospective or former executive officers, including any amendments to or terminations of any of the foregoing;
- reviewing and approving compensation payable to the executive officers for any loss or termination of office or appointment to ensure that it is consistent with contractual terms and is otherwise fair and not excessive;
- reviewing and approving, as well as approve amendments to or terminations of, any compensatory contracts or similar transactions or arrangements with such other employees as our remuneration committee determines, including employment agreements, severance arrangements, transition or consulting agreements, retirement agreements and change-in-control agreements or provisions;
- reviewing and approving our employee benefit and equity incentive plans and share schemes under Chapter 17 of the Listing Rules of The Stock Exchange of Hong Kong Limited;
- establishing, and periodically reviewing, our employee compensation plans; and
- reviewing and discussing our compensation policies and practices with management, and also periodically discuss with the board of directors and/or the nomination committee corporate succession plans for our executive officers and other key employees.

Nomination committee

Our nomination committee consists of Dr. David Sidransky, Wei Ren, Debra Yu, and Dr. Marc E. Lippman, with Dr. David Sidransky serving as chairman. Our board of directors has determined that each of Dr. David Sidransky, Wei Ren, Debra Yu, and Dr. Marc E. Lippman satisfies the “independence” requirements under the Nasdaq rules. The nomination committee assists the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees. The nomination committee is responsible for, among other things:

- reviewing and assessing and making recommendations to the board of directors regarding the desired qualifications, expertise and characteristics of sought members of the board of directors;
- reviewing and assessing and making recommendations to the board of directors regarding the structure, size and composition (including the skills, knowledge and experience) of the board of directors and making recommendations on any proposed changes to the board of directors to complement the Company’s corporate strategy;
- reviewing and assessing and making recommendations to the board of directors regarding the independence of independent non-executive directors;
- identifying individuals suitably qualified to become board members and selecting or making recommendations to the board of directors on the selection of individuals nominated for directorships;
- evaluating the performance of individual members of the board of directors eligible for re-election, and selecting, or recommending for the selection of the board of directors, the director nominees for election to the board of directors by the shareholders at the annual general meeting of the Company or any special meeting of shareholders at which directors are to be elected;
- considering the board of directors leadership structure, including the separation of the Chairman and Chief Executive Officer roles and/or appointment of a lead independent director of the board of directors, either permanently or for specific purposes, and making such recommendations to the board of directors as the nomination committee deems appropriate;
- developing and reviewing periodically the policies and procedures for considering shareholder nominees for election to the Board;
- considering director nominee recommendations from shareholders of the Company that are validly made and in accordance with applicable laws, rules and regulations and the provisions of the Company’s memorandum and articles of association;
- evaluating and recommending termination of membership of individual directors for cause or for other appropriate reasons;
- evaluating the “independence” of directors and director nominees against the independence requirements of the securities exchange on which the Company’s securities are listed, applicable rules and regulations of the SEC and other applicable laws;
- recommending to the board of directors’ nominees to fill vacancies and newly created directorships on the board of directors and nominees to stand for election as directors;
- periodically reviewing the structure and composition of each committee of the board of directors and make recommendations, if any, to the board of directors for changes to the committees of the board of directors, including changes in the structure, composition or mandate of the committees, as well as the creation or dissolution of committees; and
- overseeing the Company’s director orientation and continuing education, including making recommendations for continuing education of members of the board of directors and evaluating the participation of members of the board of directors in accordance with applicable listing standards.

Research and Development Committee

Our research and development committee consists of Dr. David Sidransky, Dr. Wang Shaomeng, with Dr. Marc E. Lippman serving as chairman. The research and development committee assists the board of directors to oversee R&D strategy, pipeline, investments, and emerging trends, ensuring alignment with the business while managing risks. The research and development committee is responsible for, among other things:

- annually review the Company’s product development pipeline;
- reviewing, evaluating and advising the Board regarding the quality, direction and competitiveness of the Company’s R&D programs; and
- reviewing and making recommendations to the Board regarding scientific merits of the Company’s internal and external investments in R&D, including any potential external investments in R&D (e.g., potential acquisitions, alliances, collaborations, equity investments, manufacturing, contracts and grants) that are submitted to the Board for approval, reporting as appropriate to any committees of the Board formed to evaluate and approve potential external investments.

Duties of directors

Under Cayman Islands law, our directors have a duty to act honestly, in good faith and with a view to our best interests. Our directors also have a duty to exercise the care, diligence and skills that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our second amended and restated memorandum and articles of association, as amended and restated from time to time, and the class rights vested thereunder in the holders of the shares. A shareholder may in certain circumstances have rights to damages if a duty owed by the directors is breached.

Our board of directors has 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 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.

Board composition and election of directors and officers

Our board of directors will consist of a minimum of two directors. Our officers are elected by and serve at the discretion of our board of directors. At each annual general meeting, one-third of the then-seated members of the board of directors, or, if the number of the members of the board of directors then seated is not three or a multiple of three, then the number nearest to, but not less than, one-third of the members of the board of directors, shall retire from office, provided that each member of the board of directors (including those appointed for a specific term) shall be subject to retirement by rotation at least once every three years. A retiring director shall be eligible for re-election at the general meeting at which a director retires. The members of our board of directors to retire by rotation shall include any member of the board of directors who desires to retire and not to seek re-election to our board of directors. Any member of the board of directors who has not been subject to retirement by rotation in the three years preceding the annual general meeting shall retire by rotation at such annual general meeting. Members of our board of directors are not required to retire upon reaching any particular age. We may from time to time in general meeting by ordinary resolution elect any person to be a director either to fill a vacancy or as an addition to the existing members of the board of directors. Any director so appointed shall be subject to retirement by rotation pursuant to our second amended and restated articles of association.

A member of our board of directors may be removed by ordinary resolution before the expiration of his or her term of office (but without prejudice to any claim which such director may have for damages for any breach of any contract with our Company) and may by ordinary resolution appoint another individual in his or her place.

A member of our board of directors shall be vacated if: (1) he or she becomes bankrupt or makes any arrangement or composition with his or her creditors; (2) he or she dies or becomes of unsound mind pursuant to an order made by any competent court or official; (3) he or she is absent from meetings of the board of directors for six consecutive months without special leave; (4) he or she is prohibited by law from serving as a member of the board of directors or is removed from office pursuant to our second amended and restated articles of association; (5) he or she resigns by delivering notice in writing to our Company at our registered office or at our headquarters or tendered at a meeting of our board of directors; (6) he or she is removed from office by an ordinary resolution of our Company; or (7) he or she is removed from office in writing signed by no less than three-fourths of the then sitting members of our board of directors.

D. Employees

As of December 31, 2025, 2024 and 2023, we had 767, 567, and 583 full-time employees. We have developed a culture of innovation where employees seek to proactively solve complex problems and challenges faced by a high growth business. We believe that we maintain a good working relationship with our employees, and we have not experienced any material labor disputes. None of our employees are represented by a labor union or party to a collective bargaining agreement.

E. Share Ownership

Information regarding the ownership of our ordinary shares by our directors and executive officers is set forth in “*Item 6. Directors, Senior Management and Employees*” and “*Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders.*”

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

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of April 20, 2026 by:

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

The calculations in the table below are based on 373,322,192 ordinary shares outstanding as of April 1, 2026.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. 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.

To the best of the Company's knowledge after having made reasonable inquiry, as of April 1, 2026, a total of 928,218 ADSs, representing 3,712,872 ordinary shares, or 1% of our outstanding ordinary shares, are held by one record holder in the United States. The holder is the depository of our ADS program. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

The address for Dajun, Yang and Yifan Zhai listed in the table is c/o Ascentage Pharma Group International, 68 Xinqing Road Suzhou Industrial Park, Suzhou, Jiangsu, China and the address for Veet Misra, Shaomeng Wang, David Sidransky, Marc E. Lippman, Debra Yu and Marina Bozilenko listed below is c/o Ascentage Pharma Group Inc., 700 King Farm Boulevard, Suite 510, Rockville, MD 20850. The address for all other persons and entities listed below are noted below.

Name of beneficial owner	Ordinary shares beneficially owned	
	Ordinary shares Number	Percentage of beneficial ownership %
5% Shareholders		
Edward Ming Guo ⁽¹⁾	59,356,611	15.9%
Takeda Pharmaceuticals International AG ⁽²⁾	24,307,322	7%
Executive Officers and Directors		
Dajun Yang, M.D., Ph.D. ⁽³⁾	59,356,611	15.9%
Yifan Zhai, M.D., Ph.D. ⁽⁴⁾	59,356,611	15.9%
Veet Misra, Ph.D.	—	*
Thomas J. Knapp	362,444	
Jin Cao	27,296	
Marina S. Bozilenko	10,472	—
Marc E. Lippman	28,652	—
Simon Dazhong Lu, Ph.D. ⁽⁵⁾	51,929	*
Wei Ren ⁽⁶⁾	19,954	*
David Sidransky, M.D. ⁽⁷⁾	21,631	*
Shaomeng Wang, Ph.D. ⁽⁸⁾	59,356,611	15.9%
Changqing Ye ⁽⁹⁾	19,954	*
Debra Yu	10,472	—
All directors and executive officers as a group (13 persons)	599,094,15	16.1%

* Represents beneficial ownership of voting power of less than 1%.

(1) Consists of (i) 11,011,767 ordinary shares held by Ming Edward Guo Dynasty Trust (as of March 1, 2025), (ii) 2,222,259 ordinary shares held by Edward Ming Guo (as of March 1, 2025), (iii) 8,565,823 ordinary shares and 2,992 options vesting in the next sixty (60) days beneficially owned by Shaomeng Wang, Ph.D., a member of our board of directors, (iv) 23,152,125 ordinary shares beneficially owned by Dajun Yang, M.D., Ph.D., our Chief Executive Officer and a member of our board of directors and (v) 14,401,645 ordinary shares beneficially owned by Yifan Zhai, M.D., Ph.D., our Chief Medical Officer. The Ming Edward Guo Dynasty Trust is a discretionary family trust established by Mr. Guo as settlor for the benefits of Dr. Guo's family members, of which South Dakota Trust is a trustee. Mr. Guo shares voting and investment control over the shares held by the Ming Edward Guo Dynasty Trust. Mr. Guo, Dr. Wang, Dr. Yang and Dr. Zhai are parties to the Concert Party Confirmation Deed, and Mr. Guo may be deemed to share voting power over the ordinary shares beneficially owned by parties to the Concert Party Confirmation Deed. See "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert party confirmation deed" for more information. Mr. Guo disclaims beneficial ownership of such shares except to the extent of his pecuniary interests therein.

- (2) Consists of 24,307,322 ordinary shares held by Takeda Pharmaceuticals International AG. Takeda Pharmaceuticals International AG is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, a public company with securities listed on the Tokyo Stock Exchange and New York Stock Exchange. Voting and investment discretion with regard to these securities is ultimately controlled by the board of directors of Takeda Pharmaceutical Company Limited.
- (3) Consists of (i) 22,054,131 ordinary shares held by the Dajun Yang Dynasty Trust, (ii) 1,097,994 ordinary shares held by Dajun Yang, M.D., Ph.D., (iii) 13,234,026 ordinary shares beneficially owned by Edward Ming Guo (as of March 1, 2025), (iv) 8,565,823 ordinary shares and 2,992 options vesting in the next sixty (60) days beneficially owned by Shaomeng Wang, Ph.D., a member of our board of directors and (v) 14,401,645 ordinary shares beneficially owned by Yifan Zhai, M.D., Ph.D., our Chief Medical Officer and Dr. Yang's spouse. The Dajun Yang Dynasty Trust is a discretionary family trust established by Dr. Yang as settlor for the benefits of Dr. Yang's family members, of which South Dakota Trust is trustee. Dr. Yang shares voting and investment control over the shares held by the Dajun Yang Dynasty Trust. Mr. Guo, Dr. Wang, Dr. Yang and Dr. Zhai are parties to the Concert Party Confirmation Deed, and Dr. Yang may be deemed to share voting power over the ordinary shares beneficially owned by parties to the Concert Party Confirmation Deed. See "*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert party confirmation deed*" for more information. Dr. Yang disclaims beneficial ownership of such shares except to the extent of his pecuniary interests therein.
- (4) Consists of (i) 14,089,111 ordinary shares held by HealthQuest Pharma Limited, (ii) 312,534 ordinary shares held by Yifan Zhai, M.D., Ph.D., (iii) 13,234,026 ordinary shares beneficially owned by Edward Ming Guo (as of March 1, 2025), (iv) 8,565,823 ordinary shares and 2,992 options vesting in the next sixty (60) days beneficially owned by Shaomeng Wang, Ph.D., and (v) 23,152,125 ordinary shares beneficially owned by Dajun Yang, M.D., Ph.D., our Chief Executive Officer and a member of our board of directors and Dr. Zhai's spouse. HealthQuest Pharma Limited is a company incorporated in the British Virgin Islands with limited liability and wholly owned by Dr. Zhai. Mr. Guo, Dr. Wang, Dr. Yang and Dr. Zhai are parties to the Concert Party Confirmation Deed, and Dr. Zhai may be deemed to share voting power over the ordinary shares beneficially owned by parties to the Concert Party Confirmation Deed. See "*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert party confirmation deed*" for more information. Dr. Zhai disclaims beneficial ownership of such shares except to the extent of her pecuniary interests therein.
- (5) Consists of 48,937 ordinary shares subject to options and 2,992 options vesting in the next sixty (60) days held by Simon Dazhong Lu, Ph.D.
- (6) Consists of 16,814 ordinary shares and 3,140 options vesting in the next sixty (60) days held by Wei Ren.
- (7) Consists of 18,491 ordinary shares and 3,140 options, vesting in the next sixty (60) days held by David Sidransky, M.D.
- (8) Consists of (i) 2,518,845 ordinary shares held by the KEW Trust, (ii) 6,024,066 ordinary shares held by the Shaomeng Wang Dynasty Trust, (iii) 1,193,032 ordinary shares held by Shaomeng Wang, Ph.D., (iv) 13,234,026 ordinary shares beneficially owned by Edward Ming Guo (as of March 1, 2025), (v) 23,152,125 ordinary shares beneficially owned by Dajun Yang, M.D., Ph.D., our Chief Executive Officer and a member of our board of directors and (vi) 14,225,367 ordinary shares beneficially owned by Yifan Zhai, M.D., Ph.D., our Chief Medical Officer. The KEW Trust is a trust established by Dr. Wang as settlor for the benefit of Dr. Wang's children. The Shaomeng Wang Dynasty Trust is a discretionary family trust established by Dr. Wang as settlor for the benefits of Dr. Wang's family members, of which South Dakota Trust is trustee. Dr. Wang shares voting and investment control over the shares held by the KEW Trust and the Shaomeng Wang Dynasty Trust. Mr. Guo, Dr. Wang, Dr. Yang and Dr. Zhai are parties to the Concert Party Confirmation Deed, and Dr. Wang may be deemed to share voting power over the ordinary shares beneficially owned by parties to the Concert Party Confirmation Deed. See "*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert party confirmation deed*" for more information. Dr. Wang disclaims beneficial ownership of such shares except to the extent of his pecuniary interests therein.
- (9) Consists of 16,814 ordinary shares and 3,140 options vesting in the next sixty (60) days held by Changqing Ye.

Voting rights

Our principal shareholders do not have different voting rights. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our Company.

Shareholders in the United States

In January 2025, we completed our U.S. initial public offering and listed ADSs representing an interest in our ordinary shares on the Nasdaq Global Market under the symbol “AAPG.” As of April 1, 2026, a total of 928,218 ADSs, representing 3,712,872 ordinary shares, or 1% of our outstanding ordinary shares, are held by one record holder in the United States. The holder is the depository of our ADS program.

B. Related Party Transactions

The following includes a summary of transactions, and any currently proposed transactions, to which we were or are expected to be a participant in which any of our executive officers, directors, or holders of more than 5% of any class of our voting securities, or any affiliate or member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest since January 1, 2025.

Healthquest acquisition

In December 2016, pursuant to an agreement between Ascentage Jiangsu and Dr. Zhai, our Chief Medical Officer, and Ms. Ren, or the Healthquest Acquisition Agreement, we acquired all equity interests in Healthquest Pharma. Prior to our acquisition, Dr. Zhai held 99.6% of the equity interests in Healthquest Pharma and Ms. Ren held the remaining 0.4%. The fair value of the total purchase consideration on the acquisition date was RMB80.4 million (US\$12.1 million).

Pursuant to the Healthquest Acquisition Agreement, we agreed to pay Dr. Zhai RMB20.0 million upon our obtaining NDA approval for Olverembatinib in China and four annual deferred milestone payments of RMB20.0 million within the first four years after the commercialization of Olverembatinib in China, representing a total of RMB80.0 million (US\$12.4 million) in the aggregate. Olverembatinib was approved in China during the year ended December 31, 2021, and we made the associated payment of RMB20.0 million. Olverembatinib was also commercialized in China during the year ended December 31, 2021, and we have made a total of three such annual deferred milestone payments since the commercialization of Olverembatinib. The remaining milestone payment of RMB20.0 million (US\$2.8 million) was made in June 2025.

Cash Bonus Payment

In June 2025, the Company paid Dr. Yang, the Company’s Chairman and CEO, a cash bonus payment of US\$ 2,394,847 in exchange for the cancellation of an aggregate of 2023 and 2024 bonus RSUs. The cash payment represented the aggregate share price of the underlying ordinary shares on the date of cancellation in June 2025. In March 2026, the remuneration committee and board of directors ratified the cash payment to Dr. Yang.

Tax Reimbursement Payment

In connection with the July 2025 placing, pursuant to which Dajun Yang Dynasty Trust, a family trust established by Dr. Yang served as vendor, the trust and/or Dr. Yang incurred certain tax liabilities, for which Dr. Yang was reimbursed by us in the amount of US\$553,648.

Private placements

See “Item 4. Information on the Company—A. History and Development of the Company”

Deed of Non-Competition

On April 24, 2019, we entered into a Deed of Non-Competition with Dr. Dajun Yang, our Chairman and Chief Executive Officer, Dr. Yifan Zhai, our Chief Medical Officer, Dr. Shaomeng Wang, a member of our board of directors, Dr. Edward Ming Guo, one of our co-founders, Ascentage Limited, and HealthQuest Pharma Limited, a company incorporated in the British Virgin Islands with limited liability, or HealthQuest Pharma Limited, collectively, the Covenantors. Pursuant to the Deed of Non-Competition, the Covenantors agreed that, during the period that the Deed of Non-Competition remains effective, they will not develop, acquire, invest in, participate in, or otherwise be involved in, directly or indirectly, whether as a shareholder, director, employee, partner, agent or otherwise in any business activity involving development of a drug candidate which carries the same target as any of Ascentage Pharma’s drug candidates, or the Restricted Activity. The Deed of Non-Competition does not restrict any of the Covenantors from acquiring a direct or indirect shareholding interest of not more than 10% in a company engaged in any Restricted Activity, provided that each Covenantor (individually or together) will not directly or indirectly own more than 10% of the total issued share capital of such company or control the exercise of more than 10% of the voting rights thereof or control the composition of the board of directors of such company.

If any of the Covenantors is offered or otherwise intends to take up any business opportunity which directly or indirectly engages in or owns the Restricted Activity, or the Competing Business Opportunity, the Covenantor must within 10 business days of identifying the Competing Business Opportunity refer the same to the Company, or the Offer Notice, and the Covenantor must not invest or participate in the Competing Business Opportunity unless such Competing Business Opportunity was rejected by the Company or an independent committee of our board of directors fails to respond within 30 business days of receipt of the Offer Notice.

The Deed of Non-Competition will cease to be effective on the earliest of (1) the date on which all Covenantors, in the aggregate, cease to beneficially own 10% of our total issued share capital and (2) with respect to each Covenantor on an individual basis, the non-competition undertaking will cease two years after termination of such Covenantor's employment relationship with Ascentage Pharma.

Concert Party Confirmation Deed

On August 11, 2018, each of (1) Dr. Dajun Yang, our Chairman and Chief Executive Officer, (2) Dr. Edward Ming Guo, (3) Dr. Shaomeng Wang, a member of our board of directors, (4) Dr. Yifan Zhai, our Chief Medical Officer, (5) HealthQuest Pharma Limited and (6) Ascentage Limited, or (1) through (6), collectively, the Concert Shareholders, entered into a Concert Party Confirmation Deed, or the Deed. Pursuant to the Deed, among other things, the Concert Shareholders agree and acknowledge that: (1) they have, and will, actively cooperate and communicate with each other to obtain and maintain consolidated control and management of our Company and adopt a consensus building approach to achieve decisions on a unanimous basis on major affairs related to our Company, including matters required to be approved by our shareholders, (2) they have not, and will not, challenge any decisions or resolutions passed in our shareholder meetings without concurrence of the other Concert Shareholders, nor will any Concert Shareholder attempt to exercise voting rights independently without concurrence of the other Concert Shareholders for any reason, (3) they have, and will, exercise their respective voting rights unanimously as a group, individually or through any entity directly or indirectly controlled by such Concert Shareholder, on all matters and resolutions proposed at shareholder meetings of our Company, and (4) each Concert Shareholder has been, and will be given, sufficient time and information to consider and discuss all corporate matters to achieve unanimity among the Concert Shareholders. The Deed remains effective unless otherwise terminated by all parties to the Deed.

Employment agreements and indemnification agreements

See the section of this Annual Report on Form 20-F titled “*Item 6. Directors, Senior Management and Employees—B. Compensation—Employment agreements and indemnification agreements.*”

Equity incentive plans and agreements

See the section of this Annual Report on Form 20-F titled “*Item 6. Directors, Senior Management and Employees—B. Compensation—Equity incentive plans.*”

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Financial Statements

See “*Item 18. Financial Statements,*” which contains our financial statements prepared in accordance with IFRS.

Legal Proceedings

From time to time, we may become involved in actions, claims, suits, and other legal proceedings arising in the ordinary course of its business, including assertions by third parties relating to intellectual property infringement, breaches of contract or warranties or employment-related matters. We are not currently a party to any actions, claims, suits or other legal proceedings the outcome of which management believes, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, financial condition, and results of operations.

Dividends and Dividend Policy

The Company has never declared or paid any cash dividends. The Company's board of directors will consider whether or not to institute a dividend policy. It is presently intended that the Company will retain its earnings for use in business operations and, accordingly, it is not anticipated that the Company's board of directors will declare dividends in the foreseeable future.

We are a holding company incorporated in the Cayman Islands. In the future, we may rely on dividends from our subsidiaries, including our PRC and U.S. subsidiaries, for our cash requirements, including any payment of dividends to our shareholders. PRC regulations may restrict the ability of our PRC subsidiary to pay dividends to us. See *"Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation—PRC regulations relating to dividend distribution."*

Our board of directors has discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, our shareholders may, subject to the provisions of our second amended and restated memorandum and articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. If we pay any dividends on our ordinary shares, we will pay those dividends which are payable in respect of the ordinary shares underlying the ADSs to the depositary, as the registered holder of such ordinary shares, and the depositary then will pay such amounts to the ADS holders in proportion to the 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.

B. Significant Changes

None.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares have been listed on the Hong Kong Stock Exchange since October 18, 2019 under the stock code “6855.” Our ADSs have been listed on the Nasdaq Global Market since January 24, 2025 under the symbol “AAPG.” Each ADS represents four ordinary shares, no par value per share.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed on the Hong Kong Stock Exchange under the stock code “6855.” Our ADSs are listed on the Nasdaq Global Market under the symbol “AAPG.”

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 are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our second amended and restated memorandum and articles of association, the Companies Act (as amended) of the Cayman Islands, or the Companies Act, and Cayman Islands common law. For more information, see our second amended and restated memorandum and articles of association attached as Exhibit 1.1 to this Annual Report on Form 20-F and “Description of Securities” attached as Exhibit 2.4 to this Annual Report on Form 20-F, each incorporated by reference herein.

The following are summaries of material provisions of our second amended and restated memorandum and articles of association and the Companies Act, insofar as they relate to the material terms of our ordinary shares.

Registered office and objects

Our registered office in the Cayman Islands is at the office of Walkers Corporate Limited, with the registered address of 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands. According to our second amended and restated memorandum and articles of association, the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by any law as provided by Section 7(4) of the Companies Act (as amended) of the Cayman Islands.

Board of directors

See “Item 6. Directors, Senior Management and Employees.”

Ordinary shares

General. Our authorized share capital is US\$50,000 consisting of 500,000,000 ordinary shares, par value US\$0.0001 per share. As of April 1, 2026, 373,322,192 ordinary shares were issued and outstanding.

All of our issued and outstanding ordinary shares are fully paid and non-assessable. Certificates representing the ordinary shares are issued in registered form. We may not issue share to bearer. Our shareholders who are non-residents of the Cayman Islands may freely hold and transfer their ordinary shares.

Dividends. The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors subject to our second amended and restated memorandum and articles of association and the Companies Act. In addition, our shareholders may, subject to the provisions of our second amended and restated memorandum and articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Our second amended and restated memorandum and articles of association provide that dividends may be declared and paid out of our profits, realized or unrealized, or from any reserve set aside from profits which our board of directors determine is no longer needed. Dividends may also be declared and paid out of share premium account or any other fund or account which can be authorized for this purpose in accordance with the Companies Act. No dividend may be declared and paid unless our directors determine that, immediately after the payment, we will be able to pay our debts as they become due in the ordinary course of business, and we have funds lawfully available for such purpose.

Voting rights. In respect of all matters subject to a shareholders’ vote, each ordinary share is entitled to one vote for each ordinary share registered in his or her name on our register of members. Voting at any meeting of shareholders is by poll, except that the chairman of the meeting may, pursuant to the Hong Kong Listing Rules, allow a resolution to be voted by a show of hands.

A quorum required for a meeting of shareholders consists of two shareholders entitled to vote at general meetings present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders’ annual general meetings. Our second amended and restated memorandum and articles of association provide that in each financial year, we will hold a general meeting as our annual general meeting in addition to any other meeting in that year and will specify the meeting as such in the notice calling it. We will hold the annual general meeting within six months after the end of our financial year. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Shareholders’ annual general meetings and any other general meetings of our shareholders may be called by a majority of our board of directors or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than one-third of the votes attaching to the issued and outstanding shares entitled to vote at general meetings, in which case the directors are obliged to call such meeting and to put the resolutions so requisitioned to a vote at such meeting; however, our second amended and restated memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders. Advance notice of at least 21 days is required for the convening of our annual general meeting and other general meetings shall be called by at least 14 days’ notice in writing in accordance with our second amended and restated memorandum and articles of association.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast by those shareholders entitled to vote who are present in person or by proxy at a general meeting, while a special resolution also requires the affirmative vote of no less than three quarters of the votes attaching to the ordinary shares cast by those shareholders entitled to vote who are present in person or by proxy at a general meeting. A special resolution will be required for important matters such as a change of name or making changes to our second amended and restated memorandum and articles of association.

Transfer of ordinary shares. Subject to the restrictions in our second amended and restated memorandum and articles of association, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four;
- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Hong Kong Stock Exchange may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer, they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year as our board may determine.

Liquidation. On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares or, on a winding up, with the sanction of a special resolution of our Company and any other sanction required by the Companies Act and subject to any special rights, privileges or restrictions as to the distribution of available surplus assets on liquidation attached to any class or classes of shares), assets available for distribution among the holders of ordinary shares will be distributed among the holders of the ordinary shares in proportion to the paid up par value of the shares held by them. If our assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the paid-up par value of the shares held by them. We are an exempted “limited liability” company registered under the Companies Act, and under the Companies Act, the liability of our members is limited to the amount, if any, unpaid on the shares respectively held by them. Our current second amended and restated memorandum of association contains a declaration that the liability of our members is so limited.

If our Company is wound up (in whatever manner), the liquidator may, with the sanction of a special resolution and any other sanction required by the Companies Act, divide among our shareholders in specie or kind the whole or any part of the assets of our Company whether the assets shall consist of property of one kind or shall consist of properties of different kinds and the liquidator may, for such purpose, set such value as it deems fair upon any one or more class or classes of property to be divided and may determine how such division shall be carried out as amongst our shareholders. The liquidator may, with the like sanction, vest any part of the assets in trustees upon such trusts for the benefit of our shareholders as the liquidator, with the like sanction, shall think fit, but so that no shareholder shall be compelled to accept any of our ordinary shares or other assets upon which there is a liability.

Calls on ordinary shares and forfeiture of ordinary shares. Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their ordinary shares in a notice served to such shareholders at least 14 clear days prior to the specified time of payment. The ordinary shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, repurchase and surrender of ordinary shares. We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders thereof, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by an ordinary resolution of our shareholders. We have made repurchases of our ordinary shares as part of our 2022 RSU Scheme during the last three years ended December 31, 2025, and we may continue to repurchase any of our ordinary shares in the future, provided that the manner and terms of such purchase have been approved by our board of directors or by ordinary resolution of our shareholders, or are otherwise authorized by our second amended and restated memorandum and articles of association. For example, at the annual general meeting of the shareholders held on May 10, 2025, the shareholders approved a resolution from the board of directors to repurchase no more than 10% of our total number of shares in issue as of the date of approval, valid until the 2026 annual general meeting of the shareholders. On March 25, 2026, our board of directors approved a resolution to submit for the approval of the shareholders at the 2026 annual general meeting, the extension of the resolution until the 2027 annual general meeting of the shareholders. In addition, on April 8, 2025, the Company announced the repurchase of 50,000 existing shares for the purpose of the 2022 RSU Scheme to satisfy the RSUs upon exercise. Under the Companies Act, the redemption or repurchase of any share may be paid out of our Company’s profits or out of the proceeds of a fresh issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if the Company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding, or (c) if the Company has commenced liquidation. In addition, our Company may accept the surrender of any fully paid share for no consideration.

Variations of rights of shares. If at any time our share capital is divided into different classes or series of shares, the rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our Company is being wound- up, may be varied with the consent in writing of three fourths of the voting rights of the holders of that class or series or with the sanction of a special resolution at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Inspection of books and records. Holders of our ordinary shares have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records (other than our current memorandum and articles of association, the register of mortgages and charges and any special resolutions passed by shareholders). However, under our second amended and restated memorandum and articles of association, during the period when our shares are listed on the Hong Kong Stock Exchange and except when our register of shareholders is closed on terms equivalent to Section 632 of the Hong Kong Companies Ordinance, any of our shareholders may inspect during business hours any register of shareholders maintained in Hong Kong without charge and require the copies of extracts of it. Under Cayman Islands law, the names of our current directors can be obtained from a search conducted at the Registrar of Companies of the Cayman Islands. The books of account shall be kept at our headquarters or at such other place or places as our board of directors thinks fit and shall always be open to the inspection of the members of our board of directors. No shareholder (unless otherwise a member of our board of directors) or other person shall have any right of inspecting any account or book or document of our Company except as conferred by the Companies Act or ordered by a court of competent jurisdiction or authorized by our board of directors or our Company at a general meeting of shareholders.

Issuance of additional shares. Our second amended and restated memorandum and articles of association authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our second amended and restated memorandum and articles of association also authorizes our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Anti-takeover provisions. Some provisions of our second amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our Company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

Exempted company. We are an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue shares with no par value;
- may obtain an undertaking against the imposition of any future taxation;
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on that shareholder’s shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Register of members

Under the Companies Act, we must keep a register of members and there should be entered therein:

- the names and addresses of our members, a statement of the shares held by each member, and of the amount paid or agreed to be considered as paid, on the shares of each member;
- the date on which the name of any person was entered on the register as a member; and
- the date on which any person ceased to be a member.

Under the Companies Act, the register of members of our Company is prima facie evidence of the matters set out therein (that is, the register of members will raise a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members is deemed as a matter of the Companies Act to have legal title to the shares as set against its name in the register of members. The shareholders recorded in the register of members will be deemed to have legal title to the shares set against their name.

If the name of any person is incorrectly entered in or omitted from our register of members, or if there is any default or unnecessary delay in entering on the register the fact of any person having ceased to be a member of our Company, the person or member aggrieved (or any member of our Company or our Company itself) may apply to the Grand Court of the Cayman Islands for an order that the register be rectified, and the Court may either refuse such application or it may, if satisfied of the justice of the case, make an order for the rectification of the register.

C. Material Contracts

We have not entered into any material contracts other than those described in “*Item 4. Information on the Company*,” “*Item 6. Directors, Senior Management and Employees*” or “*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions*” or elsewhere in this Annual Report on Form 20-F.

D. Exchange Controls

The Cayman Islands currently have no exchange control regulations or currency restrictions. For exchange control regulations or currency restrictions in China, see “*Item 4. Information on the Company—B. Business Overview—Government regulation—PRC regulation—PRC regulations relating to foreign currency exchange*.”

E. Taxation

The following discussion of Cayman Islands, PRC and U.S. federal income tax considerations related to the ownership and disposition of the ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this Annual Report on Form 20-F and is intended for general information only and does not constitute tax advice. U.S. Holders should consult their tax advisors as to the U.S. federal, state, local and non-U.S. tax considerations to them of the ownership and disposition of the ADSs and ordinary shares in their particular circumstances.

Cayman Islands taxation

According to Walkers (Hong Kong), our Cayman Islands counsel, the Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or, after execution, brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our Company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our ordinary shares 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 our ordinary shares, nor will gains derived from the disposal of our ordinary shares or ADSs be subject to Cayman Islands income or corporation tax.

Material People's Republic of China taxation

According to JunHe LLP, our PRC counsel, under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with a “de facto management body” within the PRC is considered a resident enterprise and will be subject to the enterprise income tax at the rate of 25% on its global income. The implementation rules define the term “de facto management body” as a managing body that exercises substantive and overall management and control over the production and business, personnel, accounting books and assets of an enterprise. In April 2009, the SAT issued a circular, known as 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 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: (1) the primary location of the day-to-day operational management is in the PRC; (2) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (3) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (4) at least 50% of voting board members or senior executives habitually reside in the PRC.

We believe that Ascentage Pharma is not a PRC resident enterprise for PRC tax purposes. Ascentage Pharma is not controlled by a PRC enterprise or PRC enterprise group, and we do not believe that Ascentage Pharma meets all of the conditions above. Ascentage Pharma is a company incorporated outside of the PRC. For similar reasons, we believe our other entities outside of 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 Ascentage Pharma is a PRC resident enterprise for enterprise income tax purposes or if dividends we pay to our shareholders are otherwise treated as sourced from within the PRC, we may be required to withhold a 10% withholding tax from such dividends we pay to our shareholders that are non-resident enterprises, including the holders of the ADSs. In addition, non-resident enterprise shareholders (including the ADS holders) may be subject to a 10% PRC tax on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within the PRC. It is unclear whether our non-PRC individual shareholders (including the ADS holders) would be subject to any PRC tax on dividends or gains obtained by such non-PRC individual shareholders if we are determined to be a PRC resident enterprise or if such dividends or gains are otherwise treated as sourced from within the PRC. If any PRC tax were to apply to such dividends or gains, it would generally apply at a rate of 20% unless a reduced rate is available under an applicable tax treaty (and in the case of dividends will be withheld at source). It is also unclear whether non-PRC shareholders of Ascentage Pharma would be able to obtain the benefits of any tax treaties between their country of tax residence and the PRC if Ascentage Pharma is treated as a PRC resident enterprise.

Material U.S. federal income tax considerations

The following discussion is a summary of U.S. federal income tax considerations generally applicable to the ownership and disposition of the ADSs or ordinary shares by a U.S. Holder (as defined below) and holds the ADSs or ordinary shares as “capital assets” (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion is based upon existing U.S. federal tax law (including proposed Treasury regulations and the income tax treaty between PRC and the United States, or the Treaty), which is subject to differing interpretations or change, possibly with retroactive effect. No ruling has been sought from the Internal Revenue Service, or the IRS, with respect to any U.S. federal income tax considerations described below, and there can be no assurance that the IRS or a court will not take a contrary position. This discussion, moreover, does not address the U.S. federal estate, gift, and alternative minimum tax considerations, the Medicare tax on net investment income, or any state, local and non-U.S. tax considerations, relating to the ownership or disposition of the ADSs or ordinary shares. The following summary does not address all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual circumstances or to persons in special tax situations such as:

- banks and other financial institutions;
- insurance companies;
- pension plans;
- cooperatives;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;

- dealers or traders in securities that elect to use a mark-to-market method of accounting;
- certain former U.S. citizens or long-term residents;
- tax-exempt entities (including private foundations);
- persons liable for alternative minimum tax;
- holders who acquire their ADSs or ordinary shares pursuant to any employee share option or otherwise as compensation;
- investors that will hold their ADSs or ordinary shares as part of a straddle, hedge, conversion, constructive sale or other integrated transaction for U.S. federal income tax purposes;
- investors that have a functional currency other than the U.S. dollar;
- persons that actually or constructively own 10% or more of our stock (by vote or value);
- persons that hold their ADSs or ordinary shares in connection with a trade or business outside the United States;
- persons required to accelerate the recognition of any item of gross income with respect to their ADSs or ordinary shares as a result of such income being recognized on an applicable financial statement; or
- partnerships or other entities taxable as partnerships for U.S. federal income tax purposes, or persons holding ADSs or ordinary shares through such entities;

all of whom may be subject to tax rules that differ significantly from those discussed below.

Each U.S. Holder is urged to consult its tax advisor regarding the application of U.S. federal taxation to its particular circumstances, and the state, local, non-U.S. and other tax considerations of the ownership and disposition of the ADSs or our ordinary shares.

General

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of the ADSs or ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created in, or organized under the law of, the United States or any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (A) the administration of which is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (B) that has otherwise validly elected to be treated as a U.S. person under the Code.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of the ADSs or ordinary shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. Partners in a partnerships holding the ADSs or ordinary shares are urged to consult their tax advisors regarding an investment in the ADSs or ordinary shares.

For U.S. federal income tax purposes, it is generally expected that a U.S. Holder of ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. The remainder of this discussion assumes that a U.S. Holder of the ADSs will be treated in this manner. Accordingly, deposits or withdrawals of ordinary shares for ADSs will generally not be subject to U.S. federal income tax.

Dividends

We do not currently expect to make distributions on the ADSs or ordinary shares. In the event we do make distributions of cash or other property subject to the discussion under “—Passive foreign investment company rules” below, any cash distributions paid on the ADSs or ordinary shares (including the amount of any PRC tax withheld) out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, will generally be includible in the gross income of a U.S. Holder as dividend income on the day actually or constructively received by the U.S. Holder, in the case of ordinary shares, or by the depository, in the case of ADSs. Because we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles, any distribution we pay will generally be treated as a “dividend” for U.S. federal income tax purposes. Dividends received on the ADSs or ordinary shares will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from U.S. corporations.

Individuals and 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) in the case of U.S. Holders of ADSs, the ADSs shares with respect to which the dividends are paid are readily tradable on an established securities market in the United States, or, in the case of U.S. Holders of either ADSs or ordinary shares, if we are deemed to be a PRC resident enterprise under the PRC tax law, we are eligible for the benefit the Treaty, (2) we are neither a PFIC (as defined below) nor treated as such with respect to a U.S. Holder (as discussed below) for the fiscal year in which the dividend is paid or the preceding fiscal year and (3) certain holding period and other requirements are met. We expect that the ADSs will be readily tradable on an established securities market in the United States and that we will be a qualified foreign corporation with respect to dividends (if any) paid on the ADSs. There can be no assurance that the ADSs will continue to be considered readily tradable on an established securities market in later years. Because the ordinary shares will not be listed on a U.S. exchange, dividends received with respect to ordinary shares that are not represented by ADSs may not be treated as qualified dividends. U.S. Holders are urged to consult their tax advisors regarding the availability of the lower rate for dividends paid with respect to the ADSs or ordinary shares.

If we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law, see the section of this Annual Report on Form 20-F titled “*Item 10. Additional Information—E. Taxation—People’s Republic of China Taxation*”) we may be eligible for the benefits of the Treaty. If we are eligible for such benefits, dividends we pay on our ordinary shares, regardless of whether such shares are represented by the ADSs, and regardless of whether the ADSs are readily tradable on an established securities market in the United States, would be eligible for the reduced rates of taxation described in the preceding paragraph.

For U.S. foreign tax credit purposes, dividends paid on the ADSs or ordinary shares generally will be treated as income from foreign sources and generally will constitute passive category income. If PRC withholding taxes apply to dividends paid to a U.S. Holder with respect to the ADSs or ordinary shares, such U.S. Holder may be able to obtain a reduced rate of PRC withholding taxes under the Treaty if certain requirements are met. In addition, subject to certain conditions and limitations, PRC withholding taxes on dividends that are non-refundable under the Treaty may be treated as foreign taxes eligible for credit against a U.S. Holder’s U.S. federal income tax liability.

A U.S. Holder who does not elect to claim a foreign tax credit for foreign tax 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 foreign tax credit are complex. For example, subject to temporary interim relief provided by the IRS, Treasury regulations provide that, in the absence of an election to apply the benefits of an applicable income tax treaty, in order for non-U.S. income taxes to be creditable, the relevant non-U.S. income tax rules must be consistent with certain U.S. federal income tax principles, and we have not determined whether the PRC income tax system meets these requirements. U.S. Holders are urged to consult their tax advisors regarding the availability of the foreign tax credit under their particular circumstances.

Sale or other disposition

Subject to the discussion under “—*Passive foreign investment company rules*” below, a U.S. Holder will generally recognize 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 gain or loss will generally be capital gain or loss. Individuals and other non-corporate U.S. Holders who have held the ADSs or ordinary shares for more than one year will generally be eligible for reduced tax rates. The deductibility of a capital loss may be subject to limitations. Any such gain or loss that the U.S. Holder recognizes will generally be treated as U.S. source income or loss for foreign tax credit limitation purposes, which will generally limit the availability of foreign tax credits. However, if we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law and PRC tax were to be imposed on any gain from the disposition of the ADSs or ordinary shares, a U.S. Holder that is eligible for the benefits of the Treaty may elect to treat such gain as foreign source income and claim a foreign tax credit in respect of any PRC taxes on disposition gains. Under Treasury regulations, subject to temporary interim relief provided by the IRS, if a U.S. Holder is not eligible for the benefits of the Treaty or fails to make the election to treat any gain as foreign source, then such U.S. holder may not be able to use the foreign tax credit arising from any PRC tax imposed on the disposition of the ADSs or ordinary shares. Additionally, other limitations under the foreign tax credit rules may preclude the U.S. Holder from claiming a foreign tax credit with respect to such PRC taxes. If a U.S. Holder is precluded from claiming a foreign tax credit, it is possible that any PRC taxes on disposition gains may either be deductible or reduce the amount realized on the disposition. U.S. Holders are urged to consult their tax advisors regarding the creditability of any PRC tax.

Passive foreign investment company rules

A non-U.S. corporation, such as our company, will be classified as a “passive foreign investment company”, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (1) 75% or more of its gross income for such year consists of certain types of “passive” income, or the income test, or (2) 50% or more of the amount of its assets (generally determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income, or the asset test. For this purpose, cash and assets readily convertible into cash are categorized as passive assets, and the Company’s goodwill and other unbooked intangibles are taken into account. Passive income generally includes, among other things, dividends, interest, rents, royalties (other than certain royalties treated as derived in an active conduct of a trade or business), and gains from the disposition of passive assets. We will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, at least 25% (by value) of the stock.

For purposes of the PFIC asset test, the amount of our assets will generally be determined by reference to their value, which may be determined by reference to our market capitalization. However, if we are considered to be a CFC that is not “publicly traded” for purposes of the PFIC rules during the tested period, the amount of our assets will generally be determined by reference to our adjusted bases in our assets. Further, for purposes of applying the PFIC asset test to us, if any entity in which we own 25% or more of the total value of the outstanding shares of such entity is considered to be a CFC that is not publicly traded, the amount of such entity’s assets would generally be determined by reference to its adjusted bases in its assets.

No assurances can be provided that we or any of our subsidiaries are not a CFC or will not be a CFC, and consequently, no assurances can be given that the PFIC asset test will not be applied to us based on the adjusted bases of our non-U.S. subsidiaries in their assets. Provided that we and our subsidiaries were not, and do not become, CFCs, based on the composition of our income and assets and the estimated value of our assets, which is based on our current market capitalization, we do not presently expect to be a PFIC for our current fiscal year or future fiscal years. However, no assurance can be given that we will not be a PFIC for the current fiscal year or future fiscal years because the determination of whether we will be or become a PFIC for any taxable year is a fact intensive determination made annually after the close of each taxable year that depends, in part, upon the composition and classification of our income and assets. Fluctuations in the market price of the ADSs may cause us to be or become classified as a PFIC for the current or future fiscal years because the value of our assets for purposes of the asset test, including the value of our goodwill and unbooked intangibles, may be determined by reference to the market price of our ordinary shares or ADSs from time to time (which may be volatile). Among other matters, if our market capitalization is less than anticipated or subsequently declines, we may be or become classified as a PFIC for the current fiscal year or future fiscal years.

If we are a PFIC for any fiscal year during which a U.S. Holder holds the ADSs or ordinary shares, and unless the U.S. Holder makes a mark-to-market election (as described below), the U.S. Holder will generally be subject to special tax rules on (1) any excess distribution that we make to the U.S. Holder (which generally means any distribution paid during a fiscal year to a U.S. Holder that is greater than 125% of the average annual distributions paid in the three preceding fiscal years or, if shorter, the U.S. Holder's holding period for the ADSs or ordinary shares) and (2) any gain realized on the sale or other disposition of ADSs or ordinary shares, or collectively, the Excess Distribution Rules. Under the Excess Distribution Rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the ADSs or ordinary shares;
- the amount allocated to the current fiscal year and any fiscal years in the U.S. Holder's holding period prior to the first fiscal year in which we are a PFIC, each a pre-PFIC year, will be taxable as ordinary income; and
- the amount allocated to each prior fiscal year, other than a pre-PFIC year, will be subject to tax at the highest tax rate in effect for individuals or corporations, as appropriate, for that year, increased by an additional tax equal to the interest on the resulting tax deemed deferred with respect to each such fiscal year.

If we are a PFIC for any taxable year during which a U.S. Holder holds the ADSs or ordinary shares and any of the entities in which we hold equity interests is also a PFIC, in each case, a lower-tier PFIC, such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules. U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to any of the entities in which we hold equity interests.

If we are a PFIC for any taxable year during which a U.S. Holder owns ADSs or ordinary shares, we will generally continue to be treated as a PFIC with respect to the U.S. Holder for all succeeding years during which the U.S. Holder owns the ADSs or ordinary shares, even if we cease to meet the threshold requirements for PFIC status, unless the U.S. Holder made a timely "deemed sale" election, in which case any gain on the deemed sale would be taxed under the PFIC rules described above.

As an alternative to the Excess Distribution Rules, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election with respect to such stock. If a U.S. Holder makes this election with respect to our ordinary shares or ADSs, the holder will generally (1) include as ordinary income for each fiscal year that we are a PFIC the excess, if any, of the fair market value of the ADSs and ordinary shares held at the end of the fiscal year over the adjusted tax basis of such ADSs and (2) deduct as an ordinary loss in each such fiscal year the excess, if any, of the adjusted tax basis of the ADSs over the fair market value of such ADSs and ordinary shares held at the end of the fiscal year, but such deduction will only be allowed to the extent of the amount previously included in income as a result of the mark-to-market election. The U.S. Holder's adjusted tax basis in the ADSs would be adjusted to reflect any income or loss resulting from the mark-to-market election. If a U.S. Holder makes a mark-to-market election in respect of the ADSs and we cease to be 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 a PFIC. If a U.S. Holder makes a mark-to-market election, any gain such U.S. Holder recognizes upon the sale or other disposition of the ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as ordinary loss, but such loss will only be treated as ordinary loss to the extent of the net amount previously included in income as a result of the mark-to-market election. If we cease to be a PFIC when you have a mark-to-market election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss.

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 United States Treasury regulations. For those purposes, we expect that the ADSs will be treated as marketable stock, and our ordinary shares may be treated as marketable stock as well. We anticipate that the ADSs should qualify as being regularly traded, but no assurances may be given in this regard. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be marketable stock. If we are a PFIC for any year in which a U.S. holder owns ordinary shares but before a mark-to-market election is made, the Excess Distribution Rules described above will apply to any mark-to-market gain recognized in the year the election is made.

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the general PFIC rules with respect to such U.S. Holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. Another alternative to the Excess Distribution Rules is if a U.S. Holder makes a valid "qualifying electing fund," or QEF, election.

A QEF election is available only if a U.S. Holder receives an annual information statement from the PFIC setting forth its net ordinary income and net capital gains, as determined under U.S. federal income tax principles. In the event that we are a PFIC, we cannot provide assurance that we will perform the necessary calculations or provide you with the information statement necessary to make a QEF election. Accordingly, you may not be able to make or maintain such an election with respect to your ordinary shares or ADSs.

If a U.S. Holder owns the ADSs or ordinary shares during any fiscal year that we are a PFIC, the holder must generally file an annual IRS Form 8621. You should consult your tax advisor regarding the U.S. federal income tax considerations of owning and disposing of the ADSs or ordinary shares if we are or become a PFIC, including the availability and possibility of making a mark-to-market election or qualified electing fund election.

Information reporting and backup withholding

U.S. Holders may be subject to information reporting to the IRS and U.S. backup withholding with respect to dividends on and proceeds from the sale or other disposition of the ADSs or ordinary shares that are made within the United States or through certain U.S.-related financial intermediaries. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification, or who is otherwise exempt from backup withholding and establishes this status if required to do so.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability, and a U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS and furnishing any required information. U.S. Holders should consult their tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

Information with respect to foreign financial assets

Certain U.S. Holders may be required to report information relating to the ordinary shares or ADSs if the aggregate value of these assets and certain other foreign financial assets, including equity of foreign entities, exceeds certain threshold amounts, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we are required to file with the SEC an Annual Report on Form 20-F containing financial statements audited by an independent registered public accounting firm, as well as reports on Form 6-K. The SEC maintains a website at <http://www.sec.gov> that contains reports and other information that we file with or furnish electronically to the SEC. We will also make available, free of charge, such reports and other information through our corporate website at www.ascentage.com soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report on Form 20-F.

As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act prescribing the furnishing and content of proxy statements. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. public companies whose securities are registered under the Exchange Act.

We will furnish the depositary of our ADSs with our Annual Reports on Form 20-F, which will include a review of operations and 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 RISKS

We are exposed to market risks in the ordinary course of our business. These risks primarily include credit risk and liquidity risk. For more information about financial risks that we are exposed to, see Note 26 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F.

Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in us incurring a financial loss. Our credit risk is primarily attributable to our trade and other receivables. We seek to minimize losses due to increased credit risk exposure by transacting with recognized and creditworthy third parties. All customers that wish to trade on credit terms are subject to our credit verification procedures. As of December 31, 2025 and 2024, our credit risk for receivables from third parties was RMB252.9 million (US\$36.2 million) and RMB 83.1 million, respectively.

Liquidity risk

Liquidity risk is the risk that we will encounter difficulty in meeting financial obligations due to shortage of funds. Our exposure to liquidity risk arises primarily from mismatches of the maturities of financial assets and liabilities.

We manage our liquidity risk by ensuring the availability of funding. Our primary sources of liquidity have been cash and cash equivalents raised from the issuance of ADSs, preference shares and convertible instruments and drawdown of loans and cash provided by operating activities. We monitor working capital projections to ensure that we have adequate working capital to meet current requirements.

As of December 31, 2025, we had current liabilities of RMB1,643.4 million (US\$235.0 million), as compared to RMB2,944.2 million (US\$421.0 million) of current assets. As of December 31, 2024, we had current liabilities of RMB1,166.6 million, as compared to RMB1,474.2 million of current assets. We believe that the net proceeds from the revenues from our commercial sales in China, our public and private financings, together with our existing cash and cash equivalents and our loan facility, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 20-F but may not be sufficient for us to fund any of our drug candidates through regulatory approval, which may last several years.

Interest rate risk

Our exposure to interest rate risk primarily relates to the interest income generated by excess cash, which is mostly held in interest-bearing bank deposits. We have not used any derivative financial instruments to manage our interest risk exposure. Interest-earning instruments carry a degree of interest rate risk. We have not been exposed, nor do we anticipate being exposed to material risks due to changes in interest rates. However, our future interest income may be lower than expected due to changes in market interest rates.

Inflation risk

Since our inception, inflation in China has not materially impacted our results of operations. Although we have not in the past been materially affected by inflation since our inception, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

Foreign exchange risk

We are a global business enterprise with part of our operations based in the PRC. Most of our transactions are settled in RMB, and our financial statements are presented in RMB. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in the ADSs will be affected by the exchange rate between U.S. dollar and RMB because the majority of value of our business is effectively denominated in RMB, while the ADSs representing our ordinary shares will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies is affected by changes in China's political and economic conditions and by China's foreign exchange policies, among other things. In recent years, the RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably, and it is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of RMB against the U.S. dollar would reduce the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs, servicing our outstanding debt, or for other business purposes, appreciation of the U.S. dollar against the RMB would reduce the U.S. dollar amounts available to us.

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

Fees and expenses

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of ordinary share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADSs are cancelled or reduced for any other reason, a fee of up to US\$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional fees, charges and expenses shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of up to US\$0.05 per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of up to US\$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- an amount for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian, as well as charges and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law, rule or regulation relating to foreign investment) in connection with the servicing of the shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee of up to US\$0.05 per ADS held for the direct or indirect distribution of securities (other than ADSs or rights to purchase additional ADSs) or the net cash proceeds from the public or private sale of such securities, regardless of whether any such distribution and/or sale is made by, for, or received from, or (in each case) on behalf of, the depositary, us and/or any third party (which fee may be assessed against ADR holders as of a record date set by the depositary);
- stock transfer or other taxes and other governmental charges;
- a transaction fee per cancellation request (including any cancellation request made through SWIFT, facsimile transmission or any other method of communication) as disclosed on the "Disclosures" page (or successor page) of www.adr.com (as updated by the depositary from time to time, "ADR.com") and any applicable delivery expenses (which are payable by such persons or ADS holders);
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within the banking division of the depositary, or the Bank, and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to a foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the “Disclosures” page (or successor page) of ADR.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours, and liquidity in the foreign exchange market, or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, ADR holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other fees, charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to charge and receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

The depositary anticipates reimbursing us for certain expenses incurred by us that are related to the establishment and maintenance of the ADR program upon such terms and conditions as we and the depositary may agree from time to time. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary may also agree to reduce or waive certain fees that would normally be charged on ADSs issued to or at the director of, or otherwise held by, us and/or certain holders and beneficial owners and holders and beneficial owners of ordinary shares of ours. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing ordinary 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 will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

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

A. — D. Material Modifications to the Rights of Security Holders

Not applicable.

E. Use of Proceeds

The following “Use of Proceeds” information relates to the registration statement on Form F-1, as amended (File No. 333- 284064) in relation to our U.S. initial public offering, which was declared effective by the SEC on January 23, 2025. In January 2025, we completed our U.S. initial public offering in which we issued and sold an aggregate of 8,260,144 ADSs (representing 33,040,576 ordinary shares), at a public offering price of US\$17.25 per ADS (equivalent to HK\$33.57 per ordinary share), resulting in net proceeds to us of US\$132.5 million (equivalent to HK\$1,031.4 million), after deducting underwriting discounts and commissions. J.P. Morgan Securities LLC and Citigroup Global Markets Inc. acted as joint book-running managers for our U.S. initial public offering.

The total expenses incurred in connection with our U.S. initial public offering was US\$14.6 million (equivalent to HK\$113.6 million), which included US\$10.0 million (equivalent to HK\$72.8 million) in underwriting discounts and commissions and US\$4.6 million (equivalent to HK\$33.5 million) in other offering expenses. None of the net proceeds or transaction expenses from our U.S. initial public offering were paid, directly or indirectly, to our directors or officers and persons owning 10% or more of our equity securities or our affiliates.

In July 2025, we completed our 2025 placing, pursuant to which we issued 22,000,000 ordinary shares at a price of HK\$68.60 per share. The net proceeds (after deducting all applicable costs and expenses, including commission and levies of HK\$16.7 million (US\$2.2 million) raised were HK\$1,492.5 million (US\$190.1 million).

The net proceeds received from our U.S. initial public offering and our 2025 placing are continuing to be used as described in the final prospectus filed with the SEC on January 24, 2025 and the Form 6-K filed with the SEC on July 25, 2025, respectively. As of the date of this Annual Report on Form 20-F, we have not yet substantially used the net proceeds received from these offerings.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the Company’s reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer (Principal Executive Officer) and Head of Finance (acting Principal Financial and Accounting Officer), as appropriate, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. As required by Rules 13a-15 and 15d-15 under the Exchange Act, our management, with the participation of our Chief Executive Officer and Head of Finance, acting as our Principal Financial and Accounting Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2025.

B. Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934.

In the course of auditing our consolidated financial statements as of and for the years ended December 31, 2022, 2023 and 2024, we and our independent registered public accounting firm identified one material weakness in our internal control over financial reporting. As defined in the standards established by the PCAOB, a “material weakness” is a deficiency, or a combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified relates to our insufficient accounting and financial reporting personnel with the necessary knowledge and experience with respect to the SEC’s rules and regulations and the internal control over financial reporting requirements of the Sarbanes-Oxley Act of 2002.

To remedy our material weakness, we have implemented several measures to improve our internal control over financial reporting, among others: (1) hiring additional financial reporting personnel with SEC reporting experience, (2) expanding the capabilities of existing financial reporting personnel through continuous training and education in the accounting and reporting requirements under SEC rules and regulations and (3) establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our consolidated financial statements and related disclosures.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). As of December 31, 2025, based on an assessment performed by our management on the performance of the remediation measures described above, we determined that the material weakness previously identified in our internal control over financial reporting had been remediated and our internal control over financial reporting is effective based on those criteria.

C. Attestation Report of Registered Public Accounting Firm

This Annual Report on Form 20-F does not include an attestation report of the Company's independent registered public accounting firm regarding the effectiveness of our internal control over financial reporting due to an exemption provided by the JOBS Act for emerging growth companies.

D. Changes in Internal Control over Financial Reporting

During the period covered by this Annual Report on Form 20-F, except as disclosed under “—A. Disclosure Controls and Procedures” and “—B. Management's Annual Report on Internal Control over Financial Reporting” above, there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) 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, other than the changes to remediate the material weakness as described above.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that each of Changqing Ye, Dr. Simon Dazhong Lu and Marina S. Bozilenko, an independent director and member of our audit committee, qualifies as an “audit committee financial expert,” as defined by SEC rules and regulations and in accordance with applicable Nasdaq corporate governance requirements. For a description of each directors' experience, see “Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management.”

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Business Conduct and Ethics that applies to all our directors, officers and employees, including our principal executive and principal financial officers. Our Code of Business Conduct and Ethics addresses, among other things, conflicts of interest, confidentiality, competition and fair dealing, financial matters and external reporting, our assets, as well as the process for reporting violations of the Code of Business Conduct and Ethics and employee misconduct. The Code of Business Conduct and Ethics is available on our website at www.ascentage.com. The information contained on or that can be accessed through our website is not incorporated by reference into this Annual Report on Form 20-F. The Audit Committee of our board of directors is responsible for overseeing the Code of Business Conduct and Ethics and is required to approve any waivers of the Code of Business Conduct and Ethics. We did not grant any waivers to the Code of Business Conduct and Ethics during the year ended December 31, 2025. We expect that any amendments to the Code of Business Conduct and Ethics will be disclosed on our website.

We intend to disclose on our website any amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics that applies to our directors or executive officers to the extent required under the rules of the SEC or Nasdaq. Our Code of Business Conduct and Ethics is available on our website at www.ascentage.com. The information contained on our website is not incorporated by reference in this Annual Report on Form 20-F.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The table below sets forth the total amount of services rendered by Ernst & Young Hua Ming LLP for services performed in the years ended December 31, 2025 and 2024, and breaks down these amounts by category of service:

	Year ended December 31,	
	2025	2024
	RMB (in thousands)	
Audit Fees (1)	5,100	7,900
Audit-Related Fees (2)	-	-
Tax Fees (3)	620	592
All Other Fees (4)	288	288
Total	6,008	8,780

- (1) “Audit fees” means the aggregate fees billed for professional services rendered by our independent registered public accounting firm for the audit of our annual financial statements and other audit services provided by our independent registered public accounting firm in connection with regulatory filings to the SEC.
- (2) “Audit-related fees” means the aggregate fees listed for professional services rendered by our independent registered public accounting firm related to the audit of our financial statements that are not reported under “audit fees.”
- (3) “Tax fees” means the aggregate fees billed for professional services rendered for tax compliance, tax advice and tax planning.
- (4) “Other fees” means the aggregate fees billed for corporate support services provided by our independent registered public accounting firm.

Audit Committee pre-approval policies and procedures

Pursuant to our audit committee charter, the audit committee is required to pre-approve all audit and non-audit services provided by the independent auditor, unless the engagement is entered into pursuant to appropriate preapproval policies established by the Committee or if such service falls within available exceptions under SEC rules.

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

Not applicable.

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

During the year ended December 31, 2025, no purchases of our equity securities were made by or on behalf of us or any affiliated purchaser. At the annual general meeting of the shareholders held on May 19, 2025, the shareholders approved a resolution from the board of directors to repurchase no more than 10% of our total number of shares in issue as of the date of approval, valid until the 2026 annual general meeting of the shareholders.

ITEM 16F. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

We are listed on the Nasdaq and subject to the Nasdaq rules. However, we are a “foreign private issuer” as defined by the SEC rules and regulations and, in accordance with Nasdaq Listing Rule 5615(a)(3), we may, in the future, elect to comply with certain home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of Nasdaq. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq rules.

In the event we elect to comply with certain home country governance requirements, our shareholders may be afforded less protection than they otherwise would under the Nasdaq rules applicable to U.S. domestic issuers. See “Item 3. Key Information—D. Risk Factors—Risks related to our ordinary shares and the ADSs—As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance standards; these practices may afford less protection to shareholders than they would enjoy if we comply fully with the Nasdaq corporate governance standards.”

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

Our board of directors has adopted an Insider Trading Policy that governs the purchase, sale, and other dispositions of our securities by directors, senior management, and employees that is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to us. Although the Company is not subject to the policy, the Company complies with applicable insider trading laws, rules and regulations. A copy of the Company’s Insider Trading Policy is filed as Exhibit 11.1 to this Annual Report on Form 20-F.

ITEM 16K. CYBERSECURITY

Risk Management and Strategy

Our cybersecurity risk management program is designed to protect the confidentiality, integrity, and availability of our critical systems, information and data. The policies, standards, processes and practices of our cybersecurity risk management program are part of our information security management system, or ISMS, program, which is integrated into our enterprise risk management process. Our cybersecurity risk management program includes a comprehensive set of policies and procedures to prevent accidental or intentional unauthorized modification, destruction or disclosure of confidential, proprietary, personal or otherwise critical information, including an appropriate level of security over the equipment, processes and software used to process, store and transmit information.

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

- a cybersecurity threat defense system that addresses both internal and external threats;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents and risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment;
- a security team principally responsible for managing our cybersecurity risk assessment processes, our security controls, and our response to cybersecurity incidents;
- network, host and application security;

- sensitive information protection methods, including technical safeguards, procedural requirements, and monitoring program on our corporate network;
- continuous testing of our security posture both internally and with outside vendors;
- security system effectiveness reviews with reference to applicable security standards; and
- regular cybersecurity training for employees and contractors.

To further improve the effectiveness of our cybersecurity risk management program, we engage third-party service providers, where appropriate, to assess and test the adequacy of our security controls and processes, consult best practices to address new challenges and evolving risks, or otherwise assist with aspects of our security processes. Additionally, our risk monitoring systems are regularly audited by our internal auditors as well as cybersecurity audit companies. We consider the results of external and internal audits of our risk detection and monitoring systems and implement modifications as necessary.

We also implement third-party risk management processes to identify, assess and monitor material risks from cybersecurity threats associated with key services providers that have access to our information technology systems or our confidential, proprietary, personal or otherwise critical information based on our assessment of the potential impact to our operations and respective risk profile.

We have established and seek to continuously improve effective information security governance. We apply a risk-based approach in line with our overall risk management framework to address potential gaps in security controls. The processes of our cybersecurity risk management program are aligned to ISO 27001:2022, an international standard for information security management.

As of the date of this Annual Report on Form 20-F, we have not experienced any cybersecurity incidents or risks from cybersecurity threats that have materially affected or are currently viewed as reasonably likely to materially affect, us, our business strategy, results of operations, or financial condition. However, the scope and impact of any future cybersecurity threats cannot be predicted, and there can be no assurance that our cybersecurity risk management program will be effective in preventing material cybersecurity threats in the future. For a description of the risks from cybersecurity threats that may materially affect us, including our results of operations and financial condition, see *“Item 1. Key Information—D. Risk Factors—Risks related to our industry, business and operations—We or our CROs, contractors, consultants, or other third parties may suffer system failures, security breaches, or other incidents which may have a material adverse impact to our operations and financial position, which could result in material disruption of our product development programs and adversely impact our business, financial condition or results of operations.”*

Governance

Our board of directors is responsible for overseeing cybersecurity risk as part of its enterprise risk oversight function and has delegated to the Audit Committee oversight of cybersecurity and other information technology risks. The Audit Committee oversees management’s implementation of our cybersecurity risk management program. Our board of directors receives periodic reports regarding operational, financial, strategic, regulatory and other risks to the Company, including risks and exposures associated with cybersecurity, information security and privacy matters and the steps management has taken to monitor and control such exposures. The Audit Committee and our board of directors receive biannual reports from our Chief Executive Officer regarding management’s plans to monitor and address cybersecurity risks and results from our internal audit function and third-party service-providers on their evaluation of the effectiveness of our cybersecurity risk management program.

Our cybersecurity management team, led by our head of information technology, is responsible for the day-to-day activities of our information technology systems and implementing our cybersecurity risk management program, assessing and managing our material risks from cybersecurity threats and supervising both our internal cybersecurity personnel and our external cybersecurity consultants. Our cybersecurity management team is informed about and monitors cybersecurity risks and incidents through various means, which may include briefings from internal security personnel, threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us, and alerts and reports produced by security tools deployed in the information technology environment. Our head of information technology has more than 10 years of experience in cybersecurity leadership, directing enterprise security strategies, managing cross-functional teams, and overseeing compliance with frameworks such as ISO27001. In addition, she performs risk assessments, security related policy development, and incident response coordination, ensuring alignment with business objectives. She has also implemented advanced security architectures including endpoint/virtual desktop infrastructure security, network security, data security, email security, and others and led audits for information technology security compliance as well as fostering a security-first culture through staff training and threat simulations. Based on ongoing communications with our cybersecurity management team and internal and external cybersecurity personnel, our head of information technology provides updates to our Chief Executive Officer as to our overall security controls, policies and operations and our Chief Executive Officer informs the Audit Committee and the board of directors regarding the effectiveness of our cybersecurity risk management program, associated risks and steps taken to reduce our vulnerability and mitigate impacts associated with cybersecurity threats.

PART III

ITEM 17. FINANCIAL STATEMENTS

See “Item 18. Financial Statements.”

ITEM 18. FINANCIAL STATEMENTS

The audited consolidated financial statements as required under Item 18 are attached hereto starting on page F-1 of this Annual Report on Form 20-F. The audit report of Ernst & Young Hua Ming LLP, an independent registered public accounting firm, is included herein preceding the audited consolidated financial statements.

ITEM 19. EXHIBITS

The following documents are filed as part of this Annual Report on Form 20-F or incorporated by reference herein:

Exhibit No.	Description	Incorporation by Reference			
		Form	File Number	Exhibit No.	Filing Date
1.1	Second Amended and Restated Memorandum and Articles of Association of the Registrant	F-1/A	333-284064	3.1	January 21, 2025
2.1	Form of Specimen American Depositary Receipt (included in Exhibit 4.3)	F-1/A	333-284064	4.1	January 21, 2025
2.2	Registrant’s Specimen Certificate for ordinary shares	F-1/A	333-284064	4.2	January 21, 2025
2.3	Deposit Agreement, among the Registrant, the depository and all holders and beneficial owners of American Depositary Shares	F-6	333-284315	a	January 16, 2025
2.4*	Description of Securities				
4.1#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers	F-1	333-284064	10.12	December 27, 2024
4.2	Concert Party Confirmation Deed	F-1	333-284064	10.1	December 27, 2024
4.3#	Pre-IPO Share Option Plan	F-1	333-284064	10.2	December 27, 2024
4.4#	Post-IPO Share Option Plan	F-1	333-284064	10.3	December 27, 2024
4.5	Post-IPO Share Option Plan as amended on May 19, 2025				
4.6#	2018 RSU Scheme	F-1	333-284064	10.4	December 27, 2024
4.7#	2021 RSU Scheme	F-1	333-284064	10.5	December 27, 2024
4.8	2021 RSU Scheme as amended on May 19, 2025				
4.9#	2022 RSU Scheme	F-1	333-284064	10.6	December 27, 2024
4.10	2022 RSU Scheme as amended on May 19, 2025	S-8	333-290285	10.1	September 16, 2025
4.11†	Collaboration and License Agreement between Ascentage Pharma Group Corp Limited, Guangzhou Healthquest Pharma Corp Limited, and Innovent Biologics (Suzhou) Co., LTD, Dated as of July 14, 2021	F-1	333-284064	10.7	December 27, 2024
4.12†	Amended and Restated Amended Patent License Agreement between Ascentage Pharma Group Corp Limited and the Regents of the U2022 RSU Scheme as amended on May 19, 20252				
4.13†	License Agreement between Ascentage Pharma Group Corp Limited and the Regents of the University of Michigan, dated as of December August 12, 2025				
4.14	English translation of Guangzhou Shunjian Biomedical Technology Co., Ltd. Share Transfer Agreement, dated as of December 5, 2016	F-1	333-284064	10.9	December 27, 2024
4.15#	Offer Letter between Ascentage Pharma Group Inc. and Veet Misra				
4.16#	Services Agreement between Ascentage Pharma Group Inc. and Shaomeng Wang	F-1	333-284064	10.11	December 27, 2024
4.17#	Deed of non-competition among Dr. Dajun Yang, Dr. Yifan Zhai, Dr. Shaomeng Wang, Dr. Edward Ming Guo, Ascentage Limited and HealthQuest Pharma Limited, dated April 24, 2019	F-1	333-284064	10.13	December 27, 2024

4.18†	Exclusive Option Agreement, by and among Ascentage Pharma Group Corp Limited, Guangzhou Healthquest Pharma Co., Ltd., Suzhou Ascentage Pharmaceutical Co., Ltd., Ascentage Pharma Group International and Takeda Pharmaceuticals International AG, dated as of June 14, 2024	F-1	333-284064	10.14	December 27, 2024
4.19†	Registration Rights Agreement, dated as of June 20, 2024, by and between Ascentage Pharma Group International and Takeda Pharmaceuticals AG	F-1	333-284064	10.15	December 27, 2024
4.20#	English translation of Labor Contract between Suzhou Ascentage Pharma Co., Ltd. and Dr. Dajun Yang	F-1	333-284064	10.16	December 27, 2024
4.21#	English translation of Labor Contract between Guangzhou Healthquest Pharma Co., Ltd. and Dr. Yifan Zhai	F-1	333-284064	10.17	December 27, 2024
4.22#	Offer letter between Ascentage Pharma Group Inc. and Thomas J. Knapp, as amended	F-1	333-284064	10.19	December 27, 2024
4.23#	English translation of Labor Contract between Suzhou Ascentage Pharma Co., Ltd. and Jin Cao	F-1	333-284064	10.20	December 27, 2024
8.1*	List of subsidiaries of the Registrant				
11.1*	English translation of Ascentage Pharma Group International Insider Trading Policy				
12.1*	Certification by Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934				
12.2*	Certification by Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934				
13.1*	Certification by Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code				
13.2*	Certification by Principal Financial and Accounting Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code				
15.1*	Consent of Ernst & Young Hua Ming LLP, independent registered public accounting firm				
15.2*	Consent of Walkers (Hong Kong)				
15.3*	Consent of JunHe LLP				
15.4*	Consent of Frost & Sullivan				
97.1*	Ascentage Pharma Group International Compensation Recovery Policy				
101. INS*	Inline XBRL Instance Document.				
101. SCH*	Inline XBRL Taxonomy Extension Schema Document				
101. CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101. DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101. LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101. PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Inline XBRL for the cover page of this Annual Report on Form 20-F (embedded within the Inline XBRL document)				

* Filed herewith

† Certain portions of this exhibit (indicated by asterisks) have been redacted because they are both not material and are the type that the Registrant treats as private or confidential.

Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

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

ASCENTAGE PHARMA GROUP INTERNATIONAL

Date: April 29, 2026

By: /s/ Dajun Yang

Name: Dajun Yang, M.D., Ph.D.

Title: Chairman and Chief Executive Officer

ASCENTAGE PHARMA GROUP INTERNATIONAL

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Ascentage Pharma Group International

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Ascentage Pharma Group International (the Company) as of December 31, 2025 and 2024, the related consolidated statements of profit or loss, comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as “the consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with IFRS Accounting Standards 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 audit 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/ Ernst & Young Hua Ming LLP

We have served as the Company’s auditor since 2017.

Shanghai, the People’s Republic of China

April 29, 2026

Ascentage Pharma Group International
Consolidated statements of profit or loss
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

	Notes	For the years ended December 31			
		2023	2024	2025	2025
		RMB	RMB	RMB	US\$
REVENUE					
Intellectual property		-	678,415	-	-
Products		193,535	260,835	499,272	71,395
Others		28,449	41,400	74,848	10,703
Total revenue	5	221,984	980,650	574,120	82,098
Cost of sales					
Products		(29,342)	(27,031)	(46,661)	(6,672)
Others		(1,201)	(2,054)	(2,277)	(326)
Total cost of sales		(30,543)	(29,085)	(48,938)	(6,998)
Gross profit		191,441	951,565	525,182	75,100
Other income and gains	5	59,316	57,359	103,495	14,800
Selling and distribution expenses		(195,387)	(195,998)	(353,640)	(50,570)
Administrative expenses		(181,076)	(187,125)	(246,281)	(35,218)
Research and development expenses		(706,972)	(947,245)	(1,137,448)	(162,653)
Other expenses	7	(5,203)	(9,075)	(73,599)	(10,525)
Finance costs	8	(96,057)	(64,455)	(54,070)	(7,732)
Share of profit/(loss) of a joint venture	16	1,076	(281)	314	45
LOSS BEFORE TAX	6	(932,862)	(395,255)	(1,236,047)	(176,753)
Income tax credit/(expense)	9	7,150	(10,425)	(6,940)	(992)
LOSS FOR THE YEAR		(925,712)	(405,680)	(1,242,987)	(177,745)
Attributable to:					
Ordinary equity holders of the Company		(925,637)	(405,433)	(1,242,769)	(177,714)
Non-controlling interests		(75)	(247)	(218)	(31)
		(925,712)	(405,680)	(1,242,987)	(177,745)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY					
Basic and diluted	11	(3.28)	(1.34)	(3.49)	(0.50)

Ascentage Pharma Group International
Consolidated statements of comprehensive loss
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
LOSS FOR THE YEAR	(925,712)	(405,680)	(1,242,987)	(177,745)
OTHER COMPREHENSIVE INCOME/ (LOSS)				
Other comprehensive income/ (loss) that may be reclassified to profit or loss in subsequent periods, net of tax:				
Exchange differences on translation of foreign operations	20,593	2,829	(41,574)	(5,945)
Other comprehensive income/ (loss) that will not be reclassified to profit or loss in subsequent periods, net of tax:				
Exchange differences on translation of the Company	5,666	4,120	(11,441)	(1,636)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	26,259	6,949	(53,015)	(7,581)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(899,453)	(398,731)	(1,296,002)	(185,326)
Attributable to:				
Ordinary equity holders of the Company	(899,378)	(398,484)	(1,295,784)	(185,295)
Non-controlling interests	(75)	(247)	(218)	(31)
	(899,453)	(398,731)	(1,296,002)	(185,326)

Ascentage Pharma Group International
Consolidated statements of financial position
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

		As at December 31,		
	Notes	2024	2025	2025
		RMB	RMB	US\$
NON-CURRENT ASSETS				
Property, plant and equipment	12	849,450	781,235	111,715
Right-of-use assets	13(a)	56,109	47,827	6,839
Goodwill	14	24,694	24,694	3,531
Other intangible assets	15	75,998	65,936	9,429
Investment in a joint venture	16	32,717	33,030	4,723
Financial assets at fair value through profit or loss (“FVTPL”)	17	1,141	4,000	572
Deferred tax assets	18	44,236	31,957	4,570
Other non-current assets	19	59,303	30,725	4,394
Total non-current assets		1,143,648	1,019,404	145,773
CURRENT ASSETS				
Inventories	20	6,597	28,618	4,092
Trade receivables, net	21	83,143	252,938	36,170
Prepayments, other receivables and other assets	22	123,211	192,532	27,532
Cash and bank balances	23	1,261,211	2,470,085	353,217
Total current assets		1,474,162	2,944,173	421,011
CURRENT LIABILITIES				
Trade payables	24	91,966	106,740	15,264
Other payables and accruals	25	258,098	276,666	39,563
Contract liabilities	26	37,485	37,485	5,360
Interest-bearing bank and other borrowings	27	779,062	1,222,481	174,812
Total current liabilities		1,166,611	1,643,372	234,999
NET CURRENT ASSETS		307,551	1,300,801	186,012
TOTAL ASSETS LESS CURRENT LIABILITIES		1,451,199	2,320,205	331,785

Ascentage Pharma Group International
Consolidated statements of financial position (continued)
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

		As at December 31		
	Notes	2024	2025	2025
		RMB	RMB	US\$
NON-CURRENT LIABILITIES				
Contract liabilities	26	248,460	210,224	30,062
Interest-bearing bank and other borrowings	27	889,435	757,238	108,284
Deferred tax liabilities	18	5,368	-	-
Deferred income	28	27,500	6,500	929
Other non-current liabilities		6,274	12,031	1,720
Total non-current liabilities		1,177,037	985,993	140,995
Commitments and contingencies	33, 34			
TOTAL LIABILITIES		2,343,648	2,629,365	375,994
EQUITY				
Equity attributable to ordinary equity holders of the Company				
Ordinary shares (par value of US\$0.0001 per share as of December 31, 2024 and 2025; 315,224,993 and 373,321,692 shares authorized, issued and outstanding as of December 31, 2024 and 2025, respectively)	29	214	256	37
Treasury shares	29	(8)	(2,961)	(423)
Share premium	30	6,545,129	8,916,853	1,275,093
Capital and reserves	30	(384,515)	(397,276)	(56,810)
Exchange fluctuation reserve	30	(126,071)	(179,086)	(25,609)
Accumulated losses	30	(5,770,555)	(7,013,324)	(1,002,892)
		264,194	1,324,462	189,396
Non-controlling interests		9,968	9,750	1,394
Total equity		274,162	1,334,212	190,790

Ascentage Pharma Group International
Consolidated statements of changes in equity
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

	Attributable to ordinary equity holders of the Company						Non-controlling interests	Total equity
	Share capital	Treasury shares	Share premium	Capital and reserves	Exchange fluctuation reserve	Accumulated losses		
	RMB	RMB	RMB	RMB	RMB	RMB	RMB	RMB
At January 1, 2023	180	(26,552)	5,393,029	(359,235)	(159,279)	(4,439,485)	408,658	408,658
Loss for the year	-	-	-	-	-	(925,637)	(925,637)	(925,712)
Other comprehensive income for the year:								
Exchange differences on translation of operations	-	-	-	-	26,259	-	26,259	26,259
Total comprehensive loss for the year	-	-	-	-	26,259	(925,637)	(899,378)	(899,453)
Capital contribution from a non-controlling shareholder of a subsidiary	-	-	-	-	-	-	10,290	10,290
Issue of ordinary shares	15	-	470,066	-	-	-	470,081	470,081
Repurchase of ordinary shares	-	(5,923)	-	-	-	-	(5,923)	(5,923)
Equity-settled share-based payments								
- Pre-IPO share option expenses	-	-	-	3,750	-	-	3,750	3,750
- Restricted share unit(“RSU”) expenses	-	-	-	27,753	-	-	27,753	27,753
- Exercise of Pre-IPO share options	1	-	18,354	(18,347)	-	-	8	8
- Vesting of RSUs	-	11,123	14,239	(25,362)	-	-	-	-
Equity-settled bonus	1	1	55,466	-	-	-	55,468	55,468
At December 31, 2023	197	(21,351)	5,951,154	(371,441)	(133,020)	(5,365,122)	60,417	70,632

Ascentage Pharma Group International
Consolidated statements of changes in equity (continued)
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

	Attributable to ordinary equity holders of the Company						Non-controlling interests	Total equity
	Share capital	Treasury shares	Share premium	Capital and reserves	Exchange fluctuation reserve	Accumulated losses		
	RMB	RMB	RMB	RMB	RMB	RMB	RMB	RMB
At January 1, 2024	197	(21,351)	5,951,154	(371,441)	(133,020)	(5,365,122)	60,417	70,632
Loss for the year	-	-	-	-	-	(405,433)	(247)	(405,680)
Other comprehensive income for the year:								
Exchange differences on translation of operations	-	-	-	-	6,949	-	-	6,949
Total comprehensive loss for the year	-	-	-	-	6,949	(405,433)	(247)	(398,731)
Issue of ordinary shares	17	-	533,923	-	-	-	-	533,940
Repurchase of ordinary shares	-	(1,959)	-	-	-	-	-	(1,959)
Equity-settled share-based payments								
- RSU expenses	-	-	-	20,924	-	-	-	20,924
- Exercise of Pre-IPO share options	-	-	11,379	(11,373)	-	-	-	6
- Vesting of RSUs	-	14,671	7,954	(22,625)	-	-	-	-
Equity-settled bonus	-	8,631	40,719	-	-	-	-	49,350
At December 31, 2024	214	(8)	6,545,129	(384,515)	(126,071)	(5,770,555)	9,968	274,162

Ascentage Pharma Group International
Consolidated statements of changes in equity (continued)
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

	Attributable to ordinary equity holders of the Company						Non- controlling interests	Total equity	
	Share capital	Treasury shares	Share premium	Capital and reserves	Exchange fluctuation reserve	Accumulated losses			
	Total								
	RMB	RMB	RMB	RMB	RMB	RMB			
At January 1, 2025	214	(8)	6,545,129	(384,515)	(126,071)	(5,770,555)	264,194	9,968	274,162
Loss for the year	-	-	-	-	-	(1,242,769)	(1,242,769)	(218)	(1,242,987)
Other comprehensive income for the year:									
Exchange differences on translation of operations	-	-	-	-	(53,015)	-	(53,015)	-	(53,015)
Total comprehensive loss for the year	-	-	-	-	(53,015)	(1,242,769)	(1,295,784)	(218)	(1,296,002)
Issue of ordinary shares	40	-	2,279,855	-	-	-	2,279,895	-	2,279,895
Repurchase of ordinary shares	-	(3,590)	-	-	-	-	(3,590)	-	(3,590)
Equity-settled share-based payments									
- post-IPO share option expenses	-	-	-	2,420	-	-	2,420	-	2,420
- RSU expenses	-	-	-	18,454	-	-	18,454	-	18,454
- Exercise of Pre-IPO share options	-	-	7,627	(7,623)	-	-	4	-	4
- Vesting of RSUs	1	637	25,374	(26,012)	-	-	-	-	-
Equity-settled bonus	1	-	58,868	-	-	-	58,869	-	58,869
At December 31, 2025	256	(2,961)	8,916,853	(397,276)	(179,086)	(7,013,324)	1,324,462	9,750	1,334,212
At December 31, 2025 in US\$	37	(423)	1,275,093	(56,810)	(25,609)	(1,002,892)	189,396	1,394	190,790

Ascentage Pharma Group International
Consolidated statements of cash flows

(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

		For the years ended December 31,			
	Notes	2023	2024	2025	2025
		RMB	RMB	RMB	US\$
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(932,862)	(395,255)	(1,236,047)	(176,753)
Adjustments for:					
Depreciation of property, plant and equipment	6	55,281	71,184	65,761	9,404
Depreciation of investment property	6	15,883	-	-	-
Depreciation of right-of-use assets	6	11,632	11,134	10,657	1,524
Amortization of intangible assets	6	10,399	10,851	10,062	1,439
Equity-settled share-based payments	6	31,503	20,924	20,874	2,985
(Gain)/loss on disposal of items of property, plant and equipment	6	(4)	50	18	3
Gain on disposal of leases	6	-	(85)	(685)	(99)
Fair value loss on financial assets measured at FVTPL	6	699	832	1,134	162
Fair value loss on financial liabilities measured at FVTPL	6	-	-	29,533	4,223
Fair value gain on derivative financial instruments	6	(2,822)	-	-	-
Finance costs	8	96,057	64,455	54,070	7,732
Share of (profit)/loss of a joint venture	16	(1,076)	281	(314)	(45)
Provision for inventory write-down	6	-	-	4,180	598
Foreign exchange (gain)/loss	6	(1,621)	(6,694)	10,161	1,453
		(716,931)	(222,323)	(1,030,596)	(147,374)
<u>(Increase)/ Decrease in restricted cash balances</u>		(7,936)	(96)	18,948	2,710
(Increase)/Decrease in inventories		(6,719)	9,570	(26,201)	(3,747)
(Increase)/Decrease in trade receivables		(91,537)	62,750	(169,795)	(24,281)
Increase in prepayments, other receivables and other assets		(7,841)	(14,421)	(86,337)	(12,346)
(Increase) /Decrease in other non-current assets		(3,552)	(48,950)	27,784	3,974
(Decrease) /Increase in trade payables		(23,114)	19,521	14,774	2,113
Increase in other payables and accruals		48,573	78,506	113,809	16,274
Increase /(Decrease) in contract liabilities		81,620	(3,654)	(37,485)	(5,360)
Increase in deferred income		1,360	7,740	1,000	143
Income tax paid		-	-	(29)	(4)
Net cash flows used in operating activities		(726,077)	(111,357)	(1,174,128)	(167,898)

Ascentage Pharma Group International
Consolidated statements of cash flows (continued)
(Amounts in thousands of Renminbi (“RMB”) and U.S. dollars (“US\$”), except for number of shares and per share data)

	Notes	For the years ended December 31,			
		2023	2024	2025	2025
		RMB	RMB	RMB	US\$
CASH FLOWS FROM INVESTING ACTIVITIES					
Purchases of property, plant and equipment		(46,108)	(24,289)	(27,571)	(3,942)
Proceeds from disposal of property, plant and equipment		14	-	-	-
Purchase of intangible assets		(10,736)	-	-	-
Payment of contingent consideration related to acquisition of a subsidiary		(20,000)	(9,516)	(43,342)	(6,198)
Maturity/(Placement) in time deposits with original maturity of more than three months		98,752	(312,230)	(925,139)	(132,294)
Investment in other financial assets		-	-	(4,000)	(572)
Investment in a joint venture		-	(16,000)	-	-
Net cash flows generated from/ (used in) investing activities		21,922	(362,035)	(1,000,052)	(143,006)
CASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from issue of shares		470,081	533,940	2,304,905	329,597
Treasury share purchases		(5,923)	-	(9,036)	(1,292)
Proceeds from exercise of share options		8	6	4	1
Interest paid		(92,348)	(60,556)	(51,308)	(7,337)
Proceeds from bank loans		953,500	535,923	1,240,970	177,456
Repayment of bank loans		(956,091)	(672,850)	(923,990)	(132,129)
Principal portion of lease payments		(10,766)	(8,413)	(9,717)	(1,390)
Capital contribution from non-controlling shareholders of a subsidiary		10,290	-	-	-
Listing expense paid		-	(13,283)	(11,728)	(1,677)
Net cash flows generated from financing activities		368,751	314,767	2,540,100	363,229
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS					
		(335,404)	(158,625)	365,920	52,325
Cash and cash equivalents at beginning of year		1,345,639	1,038,048	893,100	127,712
Effect of foreign exchange rate changes, net		27,813	13,677	(63,236)	(9,042)
CASH AND CASH EQUIVALENTS AT END OF YEAR		1,038,048	893,100	1,195,784	170,995
ANALYSIS OF BALANCES OF CASH AND BANK BALANCES					
Cash and cash equivalents at end of year	23	1,038,048	893,100	1,195,784	170,995
Restricted bank balances	23	24,537	24,633	5,685	812
Time deposits with original maturity of more than three months	23	31,248	343,478	1,268,616	181,410
Cash and bank balances at end of year		1,093,833	1,261,211	2,470,085	353,217

ASCENTAGE PHARMA GROUP INTERNATIONAL

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”) except for number of shares and per share data)

1. CORPORATE AND GROUP INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on November 17, 2017. The registered office of the Company is located at the office of Walkers Corporate Limited, with the registered address of 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands.

The Company is an investment holding company. The Company became the holding company of the subsidiaries upon completion of the reorganization in July 2018. The Company is a global biopharmaceutical company engaged in discovering, developing and commercializing therapies to address global medical needs primarily in hematological malignancies.

In October 2019, the Company completed its Hong Kong initial public offering with the Stock Exchange of Hong Kong Limited (the “Hong Kong Stock Exchange”). In January 2025, the Company completed its U.S. initial public offering with the NASDAQ.

Particulars of the Company’s principal subsidiaries are as follows:

Company name	Place and date of incorporation/ registration and place of business	Nominal value of issued/registered share capital	Percentage of equity interests attributable to the Company		Principal business
			Direct	Indirect	
Suzhou Ascentage Pharma Co., Ltd.*@ (“Suzhou Yasheng”)	PRC/Chinese mainland June 1, 2016	RMB 2,000,000	-	100%	Medical research and development
Guangzhou Healthquest Pharma Co., Ltd.*@ (“Healthquest Pharma”)	PRC/Chinese mainland July 3, 2012	RMB 150,000	-	100%	Clinical development and sale of products
Ascentage Pharma Group Inc.	United States of America (“United States”) November 4, 2015	US\$ 0.015	-	100%	Clinical trials
Suzhou Shenghe Innovation Works Biotech Co., Ltd.*@	PRC/Chinese mainland September 21, 2022	RMB 500	-	100%	Rental of buildings to group companies

* The English names of the companies registered in the PRC represent the best efforts made by the management of the Company in directly translating the Chinese names of these companies as no English names have been registered.

@ These entities are limited liability companies established in the PRC.

ASCENTAGE PHARMA GROUP INTERNATIONAL

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”) except for number of shares and per share data)

2. ACCOUNTING POLICIES

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with IFRS Accounting Standards (which include all International Financial Reporting Standards, International Accounting Standards (“IASs”) and interpretations) approved by the International Accounting Standards Board (the “IASB”).

These have been prepared under the historical cost convention, except for financial assets at FVTPL and derivative financial instruments which have been measured at fair value.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the “Group”) for each of the three years ended December 31, 2025. 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).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

The financial statements of the 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 continues to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognizes the fair value of any investment retained and any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognized in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

ASCENTAGE PHARMA GROUP INTERNATIONAL

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”) except for number of shares and per share data)

2. ACCOUNTING POLICIES (continued)

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted amendments to IAS 21 Lack of Exchangeability for the first time for the current year’s financial statements. The Group has not early adopted any other standard or amendment that has been issued but is not yet effective.

There were no new IFRS Accounting Standards, amendments or interpretations that became effective in 2025 that have any impact on the Group’s financial statements.

2.3 ISSUED BUT NOT YET EFFECTIVE IFRS ACCOUNTING STANDARDS

The Group has not applied the following new and amended IFRS Accounting Standards, that have been issued but are not yet effective, in these financial statements. The Group intends to apply these new and amended IFRS Accounting Standards, if applicable, when they become effective.

IFRS 18	<i>Presentation and Disclosure in Financial Statements</i> ²
IFRS 19 and its amendments	<i>Subsidiaries without Public Accountability: Disclosures</i> ²
Amendments to IFRS 9 and IFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments</i> ¹
Amendments to IFRS 9 and IFRS 7	<i>Contracts Referencing Nature-dependent Electricity</i> ¹
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IAS 21	<i>Translation to a Hyperinflationary Presentation Currency</i> ²
<i>Annual Improvements to IFRS Accounting Standards</i> – Volume 11	Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7 ¹

¹ Effective for annual periods beginning on or after January 1, 2026

² Effective for annual/reporting periods beginning on or after January 1, 2027

³ No mandatory effective date yet determined but available for adoption

The Group is in the process of making an assessment of the impact of these new and revised IFRS Accounting Standards upon initial application. So far, the Group considers that these new and revised IFRS Accounting Standards, except for IFRS 18, are unlikely to have a significant impact on the Group’s results of operations and financial position. IFRS 18 is expected to be applicable to the Group. IFRS 18 introduces new requirements on presentation within the statement of profit or loss, including specific totals and subtotals. It also requires disclosure of management-defined performance measures in a note and introduces new requirements for aggregation and disaggregation of financial information. The new requirements are expected to impact the Group’s presentation of the statement of profit or loss and disclosures of the Group’s financial performance.

ASCENTAGE PHARMA GROUP INTERNATIONAL

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”) except for number of shares and per share data)

2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES

Investments in joint venture

A joint venture is a type of joint arrangement whereby the parties that have joint control of the arrangement have rights to the net assets of the joint venture. Joint control is the contractually agreed upon sharing of control of an arrangement, which exists only when decisions about the relevant activities require the unanimous consent of the parties sharing control.

The Group's investments in joint ventures are stated in the consolidated statement of financial position at the Group's share of net assets under the equity method of accounting, less any impairment losses. Adjustments are made to bring into line any dissimilar accounting policies that may exist. The Group's share of the post-acquisition results and other comprehensive income of joint ventures is included in the consolidated statement of profit or loss and consolidated other comprehensive income, respectively. In addition, when there has been a change recognized directly in the equity of the joint venture, the Group recognizes its share of any changes, when applicable, in the consolidated statement of changes in equity. Unrealized gains and losses resulting from transactions between the Group and its joint ventures are eliminated to the extent of the Group's investments in the joint ventures, except where unrealized losses provide evidence of an impairment of the assets transferred. Goodwill arising from the acquisition of joint ventures is included as part of the Group's investments in joint ventures.

Goodwill

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred, the amount recognized for non-controlling interests and any fair value of the Group's previously held equity interests in the acquiree over the identifiable assets acquired and liabilities assumed. If the sum of this consideration and other items is lower than the fair value of the net assets acquired, the difference is, after reassessment, recognized in profit or loss as a gain on bargain purchase.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is tested for impairment annually or more frequently if events or changes in circumstances indicate that the carrying value may be impaired. The Group performs its annual impairment test of goodwill as at December 31. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group's cash-generating units, or groups of cash-generating units, that are expected to benefit from the synergies of the combination, irrespective of whether other assets or liabilities of the Group are assigned to those units or groups of units.

Impairment is determined by assessing the recoverable amount of the cash-generating unit (group of cash-generating units) to which the goodwill relates. Where the recoverable amount of the cash-generating unit (group of cash-generating units) is less than the carrying amount, an impairment loss is recognized. An impairment loss recognized for goodwill is not reversed in a subsequent period.

Where goodwill has been allocated to a cash-generating unit (or group of cash-generating units) and part of the operation within that unit is disposed of, the goodwill associated with the operation disposed of is included in the carrying amount of the operation when determining the gain or loss on the disposal. Goodwill disposed of in these circumstances is measured based on the relative value of the operation disposed of and the portion of the cash-generating unit retained.

ASCENTAGE PHARMA GROUP INTERNATIONAL

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”))
except for number of shares and per share data)

2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Fair value measurement

The Group measures its financial assets at FVTPL and derivative financial instruments at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the 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 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 reporting period.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”) except for number of shares and per share data)

2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories, deferred tax assets and non-current assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

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 the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period 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 the statement of profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

(a) the party is a person or a close member of that person's family and that person:

- (i) has control or joint control over the Group;
- (ii) has significant influence over the Group; or
- (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Related parties (continued)

A party is considered to be related to the Group if: (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;
- (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.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”)
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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

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 the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, 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:

Buildings	4.75%
Leasehold improvements	20% to 33.33%
Furniture and equipment	9.5% to 31.67%
Motor vehicles	23.75%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

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 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 stated at cost less any impairment losses and is not depreciated. It is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”))
except for number of shares and per share data)

2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Intangible assets are amortized on the straight-line basis over the following useful economic lives:

Software	3 to 10 years
Patent	14 years
License	20 years

The useful lives of software are assessed by the Group considering different purpose and usage of the software, and the authorized period for use. The useful life of patent is assessed by the Group based on the remaining and foreseeable patent protection period after acquisition. The useful life of a purchased license is assessed by considering the expected usage of the license by the Group.

Research and development costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred. During the reporting period, all expenses incurred for research and development activities were regarded as research expenses and therefore were 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.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”) except for number of shares and per share data)

2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Leases (continued)

Group as a lessee (continued)

(a) Right-of-use assets

Right-of-use assets are recognized at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less 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:

Leasehold land	30 years
Buildings	2 to 7 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

The Group’s lease liabilities are included in interest-bearing bank and other borrowings.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Leases (continued)

Group as a lessee (continued)

(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 machinery and 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.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost and fair value through profit and loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at FVTPL, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortized cost, 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.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Investments and other financial assets (continued)

Initial recognition and measurement (continued)

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.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognized on the trade date, that is, the date that the Group commits to purchase or sell the asset.

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 when the asset is derecognized, modified or impaired.

Financial assets at FVTPL

Financial assets at FVTPL 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.

Dividends on the equity investments are also recognized as other income in the statement of profit or loss when the right of payment has been established.

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.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Derecognition of financial assets (continued)

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognize the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognizes an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 120 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.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Impairment of financial assets (continued)

General approach (continued)

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 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 each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at FVTPL, loans and borrowings, or 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 payables, financial liabilities included in other payables and accruals, interest-bearing bank and other borrowings, long-term payables and other current and non-current liabilities.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Financial liabilities (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 designated upon initial recognition as at fair value through profit or loss.

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.

Financial liabilities at amortized cost (trade and other payables, and borrowings)

After initial recognition, trade and other payables, and interest-bearing 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 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.

Derecognition of financial liabilities

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognized in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, or to realize the assets and settle the liabilities simultaneously.

Derivative financial instruments

Initial recognition and subsequent measurement

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.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Treasury shares

Own equity instruments which are reacquired and held by the Company or the Group (treasury shares) are recognized directly in equity at cost. No gain or loss is recognized in the statement of profit or loss on the purchase, sale, issue or cancellation of the Group’s own equity instruments.

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined on the first-in, first-out basis, in the case of work in progress and finished goods, comprises direct materials, direct labor, contract manufacturing fee and an appropriate proportion of overheads. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

Cash and cash equivalents in the statements of cash flows comprise cash on hand and at banks, and short-term highly liquid deposits with a maturity of generally within three months that are readily convertible into known amounts of cash, subject to an insignificant risk of changes in value and held for the purpose of meeting short-term cash commitments.

For the purpose of the consolidated statements of financial positions, cash and bank balances comprise cash and cash equivalents as defined above, restricted bank balances and time deposits with original maturity of more than three months as defined above.

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 Group expects some or all of a provision to be reimbursed, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the statement of profit or loss net of any reimbursement.

When the effect of discounting is material, the amount recognized for a provision is the present value at the end of the reporting date of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in the statement of profit or loss.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items 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 each 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 reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Income tax (continued)

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- (i) 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 does not give rise to equal taxable and deductible temporary differences; and
- (ii) in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, and 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:

- (i) 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 does not give rise to equal taxable and deductible temporary differences; and
- (ii) in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognized to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at the end of each reporting period 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 realize 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.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

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.

The government grants whose primary condition is to compensate for research and development projects or other than purchase, construct or otherwise acquire long-term assets are designated as grants related to income. Some of the grants related to income have future related costs expected to be incurred and require the Group to comply with conditions attached to the grants and the government to acknowledge the compliance of these conditions. These grants related to income are recognized as deferred income in the consolidated statement of financial position and transferred to profit or loss when related costs are subsequently incurred, and the Group received government acknowledgment of compliance.

Other government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Revenue recognition (continued)

Revenue from contracts with customers (continued)

(a) Sale of products

Revenue from the sale of products is recognized at the point in time when control of the asset is transferred to the customer, generally on acceptance of the products.

(b) Commercialization rights

The Group provides commercialization, development and branding rights (collectively, “Commercialization Rights”) to customers for an agreed upon commercialization period ending ten years from the date of the first sale of the product as stipulated in the relevant agreement. The consideration for Commercialization Rights includes upfront payment, development and regulatory milestones payments and commercialization milestones payments.

Development and regulatory milestones payments are fully constrained until the period in which those regulatory approvals are achieved due to the inherent uncertainty with the approval process and included in the transaction price in the period regulatory approval is obtained. Upfront payment and development and regulatory milestones payments are recorded under contract liabilities and recognized as revenue over time during the commercialization period on a straight-line basis.

Commercialization milestone payments based on the level of sales are recognized at a point in time when the later of the following events occurs: (i) the related sale occurs, or (ii) the performance obligation to which commercialization milestones payments have been allocated has been satisfied.

(c) Intellectual property income

Intellectual property income is recognized at the point in time at which the non-patented intellectual property is granted to the customer because the Company will not undertake activities that affect such intellectual property.

The consideration for intellectual property income comprises a fixed element and a variable element. Variable element is recognized as the transaction price when the Company can conclude that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

(d) Others

The Group provides consulting services to its customers through contracts. Depending on the contract, revenue is recognized over time as the service is rendered, or at the point in time as the service is completed and accepted.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Revenue recognition (continued)

Other 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.

Contract liabilities

A contract liability is recognized when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods or services. Contract liabilities are recognized as revenue when the Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

Share-based payments

The Company operates share incentive plans which include the pre-IPO share option scheme, the post-IPO share option scheme, 2018 restricted share unit scheme (the “2018 RSU Scheme”), 2021 restricted share unit scheme (the “2021 RSU Scheme”) and 2022 restricted share unit scheme (the “2022 RSU Scheme”). Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments (“equity-settled transactions”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted, further details of which are given in note 31 to the 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 reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Share-based payments (continued)

Where the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments or is otherwise beneficial to the employee as measured at the date of modification. Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of loss per share.

Other employee benefits

Pension scheme

The employees of the Group's subsidiaries which operate in the Chinese mainland are required to participate in a central pension scheme operated by the local municipal government. The subsidiaries operating in Chinese mainland 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 Group implemented a safe harbor defined contribution 401(k) savings plan (the “401(k) Plan”) for U.S. employees. The 401(k) Plan covers all U.S. employees and allows participants to defer a portion of their annual compensation on a pre-tax basis. In addition, the Company implemented a matching contribution to the 401(k) Plan, matching 100% of an employee's contribution up to a maximum of 6% of the participant's annual base salary. Such matching contribution vests when made.

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. 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.

Events after the reporting period

If the Group receives information after the reporting period, but prior to the date of authorization for issue, about conditions that existed at the end of the reporting period, it will assess whether the information affects the amounts that it recognizes in its financial statements. The Group will adjust the amounts recognized in its financial statements to reflect any adjusting events after the reporting period and update the disclosures that relate to those conditions in light of the new information. For non-adjusting events after the reporting period, the Group will not change the amounts recognized in its financial statements but will disclose the nature of the non-adjusting events and an estimate of their financial effects, or a statement that such an estimate cannot be made, if applicable.

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2. ACCOUNTING POLICIES (continued)

2.4 MATERIAL ACCOUNTING POLICIES (continued)

Foreign currencies

These financial statements are presented in RMB. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognized in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognized in other comprehensive income or profit or loss is also recognized in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of 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 overseas subsidiaries are currencies other than the RMB. As at the end of the reporting period, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognized in other comprehensive income and accumulated in the exchange fluctuation reserve, except to the extent that the differences are attributable to non-controlling interests. On disposal of a foreign operation, the cumulative amount in the reserve relating to that particular foreign operation is recognized in the statement of profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on acquisition are treated as assets and liabilities of the foreign operation and translated at the closing rate.

For the purpose of the consolidated statements of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

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3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of 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.

Judgements

In the process of applying the Group’s accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognized in the financial statements:

Revenue from contracts with customers

The Group applied the following judgements that significantly affect the determination of the amount and timing of revenue from contracts with customers:

Commercialization rights contracts include variable consideration based on future events. In estimating the variable consideration, the Group is required to use either the expected value method or the most likely amount method based on which method better predicts the amount of consideration to which it will be entitled.

Given that the payments of certain variable consideration are not within the control of the Group, such as regulatory approvals, relevant consideration is not considered until relevant approvals are obtained. The Group determines that the most likely amount method is the appropriate method to estimate the variable consideration. When the Group can conclude that it is highly probable that there will not be a subsequent reversal of a significant amount of revenue, the variable consideration will be included in the transaction price.

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.

Taxes

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 the level of future taxable profits, together with future tax planning strategies. The Group has carried forward tax losses of RMB 4,425,237 and RMB5,347,045 (US\$764,617) as of December 31, 2024 and 2025, respectively, of which related deferred tax assets of RMB3,523 and RMB12,373 (US\$1,769) have been recognized as of December 31, 2024 and 2025, respectively. Deferred tax assets have not been recognized in respect of losses that have arisen in subsidiaries that have been loss-making for some time, and it is not considered probable that taxable profits will be available against which the tax losses can be utilized.

If the Group was able to recognize all unrecognized deferred tax assets, net loss would have decreased and equity would have increased by RMB1,119,913, RMB1,321,638 and RMB1,572,664 (US\$224,889) during the years ended December 31, 2023, 2024 and 2025, respectively. Further details on taxes are disclosed in Note 9.

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4. OPERATING SEGMENT INFORMATION

For management purposes, the Group has only one reportable operating segment, which is discovering, developing and commercializing therapies to address global medical needs primarily in hematological malignancies Management monitors the operating results of the Group’s operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment. Therefore, no analysis by operating segment is presented.

Geographical information

(a) Revenue from external customers

	For the years ended December 31,			
	2023 RMB	2024 RMB	2025 RMB	2025 US\$
Chinese mainland	221,984	302,235	574,120	82,098
Switzerland	-	678,415	-	-
Total revenue	221,984	980,650	574,120	82,098

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

(b) Non-current assets

	As at December 31,			
	2023 RMB	2024 RMB	2025 RMB	2025 US\$
Chinese mainland	1,088,733	1,090,914	978,233	139,885
United States	2,665	4,474	4,489	642
Others	24	444	35	5
Total non-current assets	1,091,422	1,095,832	982,757	140,532

The non-current assets information above is based on the locations of the assets and excludes financial instruments and deferred tax assets.

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4. OPERATING SEGMENT INFORMATION (continued)

Information about major customers

Revenue from customers amounting to over 10% of the total revenue of the Group in the reporting period is as follows:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Customer A	107,323	229,895	436,644	62,439
Customer B	N/A*	678,415	N/A*	N/A*
Customer C	35,021	N/A*	N/A*	N/A*
Customer D	30,623	N/A*	N/A*	N/A*
	<u>172,967</u>	<u>908,310</u>	<u>436,644</u>	<u>62,439</u>

* These customers generated less than 10% of the total revenue of the Group during the years ended December 31, 2023, 2024 and 2025.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

Revenue from contracts with customers

(a) Disaggregated revenue information

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Types of goods or services				
Intellectual property income	-	678,415	-	-
Sales of products	193,535	260,835	499,272	71,395
Commercialization rights income	26,049	37,485	72,629	10,386
Others	2,400	3,915	2,219	317
Total	<u>221,984</u>	<u>980,650</u>	<u>574,120</u>	<u>82,098</u>
Timing of revenue recognition				
<i>At a point in time</i>				
Intellectual property income	-	678,415	-	-
Sales of products	193,535	260,835	499,272	71,395
Commercialization rights income	-	-	35,144	5,026
<i>Over time</i>				
Commercialization rights income	26,049	37,485	37,485	5,360
Others	2,400	3,915	2,219	317
Total	<u>221,984</u>	<u>980,650</u>	<u>574,120</u>	<u>82,098</u>

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5. REVENUE, OTHER INCOME AND GAINS (continued)

Revenue from contracts with customers (continued)

(a) Disaggregated revenue information (continued)

The following table shows the amounts of revenue recognized in the current reporting period that were included in the contract liabilities at the beginning of the reporting period:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Commercialization rights income	26,049	37,485	37,485	5,360

(b) Performance obligations

Information about the Group’s performance obligations is summarized below:

Intellectual property income

The intellectual property income is recognized at the point of time upon the customer obtains the right to use the non-patented intellectual property as there are no ongoing activities that significantly affect the intellectual property.

Sales of products

The performance obligation is satisfied upon acceptance of the products and payment is generally due within 45 to 120 days from the date of billing.

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5. REVENUE, OTHER INCOME AND GAINS (continued)

Revenue from contracts with customers (continued)

(b) Performance obligations (continued)

Commercialization rights

The performance obligation is satisfied over time as commercialization rights are granted for an agreed upon commercialization period ending ten years from the date of the first sale of the product as stipulated in the relevant agreement. Among these, revenue from sales-based commercialization milestone payments is recognized at a point in time when the related sale occurs. Upfront payment in advance is required, and the development and regulatory milestones payments and commercialization milestones payments are generally due within 120 days from the date of billing.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at December 31, 2024 and 2025 are as follows:

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Amounts expected to be recognized as revenue:			
Within one year	37,485	37,485	5,360
After one year	248,460	210,224	30,062
Total	285,945	247,709	35,422

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognized mainly related to commercialization rights, which have been partially recognized during the reporting period (note 26). The amounts disclosed above do not include variable consideration which is constrained.

Other income and gains

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Bank interest income	32,409	37,840	82,125	11,744
Government grants related to income	19,358	9,073	14,496	2,073
Foreign exchange gain, net	1,621	6,694	-	-
Rental income	400	2,324	4,989	713
Fair value gain on derivative financial instruments	2,822	-	-	-
Gain on disposal of items of property, plant and equipment	4	-	-	-
Others	2,702	1,428	1,885	270
Total other income and gains	59,316	57,359	103,495	14,800

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6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

Notes	For the years ended December 31,			
	2023 RMB	2024 RMB	2025 RMB	2025 US\$
Cost of inventories sold	29,342	27,031	42,481	6,074
Cost of services provided	1,201	2,054	2,277	326
Write-down of inventories to net realizable value	20	-	4,180	598
Depreciation of property, plant and equipment**	12	55,281	71,184	9,404
Depreciation of investment property**		15,883	-	-
Depreciation of right-of-use assets**	13(a)	11,632	11,134	1,524
Amortization of intangible assets**	15	10,399	10,062	1,439
Research and development costs		706,972	947,245	162,653
Employee benefit expense (including directors’ remuneration):				
Wages and salaries		337,381	367,008	57,799
Equity-settled share-based payment expenses**	31	31,503	20,924	2,985
Pension scheme contributions (defined contribution scheme)*		30,705	34,404	5,038
Total		399,589	422,336	65,822
Fair value (gain)/loss, net:				
Derivative financial instruments		(2,822)	-	-
Financial assets at FVTPL		699	832	162
Financial liabilities at FVTPL	36(b)	-	-	29,533
(Gain)/Loss on disposal of items of property, plant and equipment		(4)	50	3
Gain on disposal of items of lease		-	(85)	(99)
Lease payments not included in the measurement of lease liabilities	13(c)	181	238	47
Government grants related to income		(19,358)	(9,073)	(2,073)
Bank interest income		(32,409)	(37,840)	(11,744)
Auditors’ remuneration		2,550	7,900	729
Donations		3,988	6,322	3,345
Penalty		24	1,425	826
Foreign exchange (gain)/loss, net		(1,621)	(6,694)	1,453

* There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

** The depreciation of property, plant and equipment, the depreciation of investment property, the depreciation of right-of-use assets, the amortization of intangible assets and the equity-settled share-based payment expenses for the years are included in “Cost of Sales”, “Research and development expenses”, “Selling and distribution expenses” and “Administrative expenses” in the consolidated statements of profit or loss.

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7. OTHER EXPENSES

	For the years ended December 31,			
	2023 RMB	2024 RMB	2025 RMB	2025 US\$
Fair value loss on financial liabilities at FVTPL	-	-	29,533	4,223
Donations	3,988	6,322	23,395	3,345
Foreign exchange loss	-	-	10,161	1,453
Penalty	24	1,425	5,777	827
Fair value loss on financial assets at FVTPL	699	832	1,134	162
Loss on disposal of items of property, plant and equipment	-	50	18	3
Others	492	446	3,581	512
Total	5,203	9,075	73,599	10,525

8. FINANCE COSTS

An analysis of finance costs is as follows:

	For the years ended December 31,			
	2023 RMB	2024 RMB	2025 RMB	2025 US\$
Interest on bank loans and other borrowings	91,690	61,555	51,812	7,409
Interest on lease liabilities (note 13(b))	1,321	1,498	1,118	160
Interest on long-term payables	3,046	1,402	1,140	163
Total	96,057	64,455	54,070	7,732

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9. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, the Company and Ascentage Pharma Group International are not subject to tax on income or capital gain arising in the Cayman Islands. Additionally, upon payments of dividends by these companies to its shareholders, no Cayman Islands withholding tax will be imposed.

Hong Kong

The subsidiaries incorporated in Hong Kong are subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong. For the years ended December 31, 2023, 2024 and 2025, the Company did not make any provisions for Hong Kong profits tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented.

United States

The subsidiary operating in the United States is subject to tax at a maximum of 21.36% and 21.61%, respectively, for the years ended December 31, 2024 and 2025. No provision for income tax has been made as the Group had no assessable profits earned in the United States during the reporting period.

A requirement to capitalize and amortize previously deductible research and experimental expenses resulting from a change in Section 174 made by the Tax Cuts and Jobs Act of 2017 (the “TCJA”) became effective on January 1, 2022. Under the TCJA, the Company is required to capitalize and subsequently amortize R&D expenses over five years for research activities conducted within the U.S. and fifteen years for research activities conducted outside of the U.S.

In July 2025, the One Big Beautiful Bill Act (“OBBA”) was enacted, which reinstated current deductibility of domestic research and experimental expenditures and provided an election to accelerate the recovery of previously capitalized costs. The Company did not elect to accelerate the deduction of previously capitalized domestic research and experimental expenditures and will continue to amortize such costs over the remaining statutory periods.

Chinese mainland

The Company’s subsidiaries domiciled in the PRC are subject to the statutory rate of 25%, in accordance with the Enterprise Income Tax law (the “EIT Law”), which was effective since January 1, 2008, except for the following entities which are eligible for a preferential tax rate.

Healthquest Pharma was qualified as a High and New Technology Enterprise (“HNTE”) and was subject to a preferential rate of 15% for three years from 2022 to 2024. In 2025, Healthquest Pharma was no longer qualified as a HNTE and thus subject to the statutory tax rate of 25%.

Suzhou Yasheng was recognized as a qualified HNTE under the EIT Law by the relevant government authorities and is subject to a preferential rate of 15% for three years from 2023 to 2025.

Dividends, interest, rent or royalties payable by the Company’s PRC subsidiaries, to non-PRC resident enterprises, and proceeds from any such non-resident enterprise investor’s disposition of assets (after deducting the net value of such assets) shall be subject to 10% withholding tax, unless the respective non-PRC resident enterprise’s jurisdiction of incorporation has a tax treaty or arrangements with China that provides for a reduced withholding tax rate or an exemption from withholding tax.

The current and deferred components of the income tax (credit)/expense are as follows:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Current	-	-	29	4
Deferred (note 18)	(7,150)	10,425	6,911	988
Total income tax (credit)/expense for the year	(7,150)	10,425	6,940	992

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9. INCOME TAX (continued)

Reconciliation between the income tax expense/(credit) computed by applying the statutory tax rate to loss before income tax and the actual provision for income tax is as follows:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Loss before tax	(932,862)	(395,255)	(1,236,047)	(176,753)
Income tax computed at the statutory tax rate	(244,549)	(70,114)	(287,881)	(41,166)
Lower tax rate for a specific entity	59,396	7,112	59,759	8,545
Statutory income and expense	2,824	(17,534)	(12,900)	(1,845)
Items not subject to tax	(4,093)	(7,236)	(7,533)	(1,076)
Items not deductible for tax	9,192	24,045	49,582	7,091
Research and development super-deduction	(67,525)	(75,135)	(48,919)	(6,995)
(Gain)/loss attributable to joint ventures	(269)	71	(78)	(11)
Provision to return	23,311	(35,342)	68,391	9,779
Effect of tax rate changes on deferred taxes	(56,104)	(10,822)	(71,206)	(10,183)
Uncertain tax position	-	23,665	14,236	2,036
Effect of withholding tax on the interest income of the Group’s HK subsidiary	-	-	29	4
Tax loss expired	-	31,670	29,628	4,237
Deductible temporary differences not recognized	33,235	71,465	49,919	7,138
Tax losses not recognized	237,432	68,580	163,913	23,438
Income tax (credit)/expense at the Group’s effective rate	(7,150)	10,425	6,940	992

Note: The disclosure presentation of previous periods has been adjusted to be in line with the 2025 disclosure presentation of “Tax loss expired” to ensure consistency.

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The board of directors resolved not to declare any final dividend for the years ended December 31, 2023, 2024 and 2025.

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 356,130,452 (2024: 302,062,104, 2023: 282,299,269) outstanding during the year, as adjusted to reflect the rights issued during the year.

No adjustment has been made to the basic loss per share amounts presented for the years ended December 31, 2023, 2024 and 2025 in respect of a dilution as the impact of the options and RSUs outstanding had an anti-dilutive effect on the basic loss per share amounts presented.

The calculation of basic loss per share is based on:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
<u>Loss</u>				
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	(925,637)	(405,433)	(1,242,769)	(177,714)
		Number of shares		
		2023	2024	2025
<u>Shares</u>				
Weighted average number of ordinary shares outstanding during the year used in the basic loss per share calculation#		282,299,269	302,062,104	356,130,452

The weighted average number of shares was after taking into account the effect of treasury shares held.

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12. PROPERTY, PLANT AND EQUIPMENT

	Buildings	Leasehold	Furniture and	Motor	Construction	Total
	RMB	improvements	equipment	vehicles	in progress	RMB
		RMB	RMB	RMB	RMB	
December 31, 2024						
At January 1, 2024:						
Cost	834,913	29,218	179,256	609	12,650	1,056,646
Accumulated depreciation	(65,137)	(11,517)	(73,771)	(406)	-	(150,831)
Net carrying amount	<u>769,776</u>	<u>17,701</u>	<u>105,485</u>	<u>203</u>	<u>12,650</u>	<u>905,815</u>
At January 1, 2024, net of accumulated depreciation	769,776	17,701	105,485	203	12,650	905,815
Additions	-	-	2,059	-	12,807	14,866
Disposals	-	-	(50)	-	-	(50)
Depreciation provided during the year (note 6)	(39,599)	(6,896)	(24,569)	(120)	-	(71,184)
Transfers	1,105	15,010	2,049	-	(18,164)	-
Exchange realignment	-	-	3	-	-	3
At December 31, 2024, net of accumulated depreciation	<u>731,282</u>	<u>25,815</u>	<u>84,977</u>	<u>83</u>	<u>7,293</u>	<u>849,450</u>
At December 31, 2024:						
Cost	836,018	44,239	182,734	609	7,293	1,070,893
Accumulated depreciation	(104,736)	(18,424)	(97,757)	(526)	-	(221,443)
Net carrying amount	<u>731,282</u>	<u>25,815</u>	<u>84,977</u>	<u>83</u>	<u>7,293</u>	<u>849,450</u>

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12. PROPERTY, PLANT AND EQUIPMENT (continued)

	Buildings RMB	Leasehold improvements RMB	Furniture and equipment RMB	Motor vehicles RMB	Construction in progress RMB	Total RMB
December 31, 2025						
At January 1, 2025:						
Cost	836,018	44,239	182,734	609	7,293	1,070,893
Accumulated depreciation	(104,736)	(18,424)	(97,757)	(526)	-	(221,443)
Net carrying amount	731,282	25,815	84,977	83	7,293	849,450
At January 1, 2025, net of accumulated depreciation	731,282	25,815	84,977	83	7,293	849,450
Additions	-	3,270	2,635	427	11,229	17,561
Disposals	-	-	(18)	-	-	(18)
Depreciation provided during the year (note 6)	(37,117)	(10,374)	(18,157)	(113)	-	(65,761)
Transfers	2,802	13,242	368	-	(16,412)	-
Deficit on adjustment	(19,982)	-	-	-	-	(19,982)
Exchange realignment	-	-	(15)	-	-	(15)
At December 31, 2025, net of accumulated depreciation	676,985	31,953	69,790	397	2,110	781,235
At December 31, 2025:						
Cost	818,838	60,734	185,546	1,036	2,110	1,068,264
Accumulated depreciation	(141,853)	(28,781)	(115,756)	(639)	-	(287,029)
Net carrying amount	676,985	31,953	69,790	397	2,110	781,235
Net carrying amount in US\$	96,808	4,569	9,980	56	302	111,715

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13. LEASES

The Group as a lessee

The Group has lease contracts for land and buildings. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 30 years, and no ongoing payments will be made under the terms of these land leases. Leases of buildings generally have lease terms between 2 and 7 years. Other leases generally have lease terms of 12 months or less and/or are individually of low value. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the year are as follows:

	Buildings	Leasehold land	Total	Total
	RMB	RMB	RMB	US\$
As at January 1, 2024	23,654	27,598	51,252	7,329
Additions	17,108	-	17,108	2,446
Depreciation charge (note 6)	(10,004)	(1,130)	(11,134)	(1,592)
Disposal	(1,067)	-	(1,067)	(153)
Exchange realignment	(50)	-	(50)	(7)
As at December 31, 2024 and January 1, 2025	29,641	26,468	56,109	8,023
Additions	5,047	-	5,047	722
Depreciation charge (note 6)	(9,527)	(1,130)	(10,657)	(1,524)
Disposal	(2,675)	-	(2,675)	(382)
Exchange realignment	3	-	3	-
As at December 31, 2025	22,489	25,338	47,827	6,839

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13. LEASES (continued)

The Group as a lessee (continued)

(b) Lease liabilities

The carrying amount of lease liabilities (included under interest-bearing bank and other borrowings) and the movements during the year are as follows:

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Carrying amount at January 1	22,681	30,232	4,323
New leases	17,108	5,047	722
Accretion of interest recognized during the year (note 8)	1,498	1,118	160
Payments	(9,911)	(10,835)	(1,549)
Exchange realignment	8	(6)	(1)
Disposal	(1,152)	(3,360)	(481)
Carrying amount at December 31	30,232	22,196	3,174
Analyzed into:			
Current portion	9,439	7,283	1,041
Non-current portion	20,793	14,913	2,133

The maturity analysis of lease liabilities is disclosed in note 39 to the consolidated financial statements.

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

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Interest on lease liabilities (note 8)	1,498	1,118	160
Depreciation charge of right-of-use assets	11,134	10,657	1,524
Expense relating to short-term leases (included in administrative expenses) (note 6)	238	329	47
Total amount recognized in profit or loss	12,870	12,104	1,731

(d) The total cash outflow for leases and future cash outflows relating to leases that have not yet commenced are disclosed in notes 32(c) and 33(b), respectively, to the consolidated financial statements.

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14. GOODWILL

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Cost	24,694	24,694	3,531
Accumulated impairment	-	-	-
Total	24,694	24,694	3,531

The carrying amount of goodwill as at December 31, 2024 and 2025 was allocated to the cash-generating unit (“CGU”) of Healthquest Pharma.

Impairment testing of goodwill

The recoverable amount of the cash-generating unit has been determined based on a value in use calculation using cash flow projections approved by senior management. The cash flows of the unit are projected based on the forecasted sales of the new drug after the approval of the new drug application (“NDA”) and within the patent protection period. No revenue nor cash flow has been forecasted after the expiration of the patent.

Assumptions were used in the value in use calculation of the cash-generating unit for the reporting period.

The following describes each key assumption on which management has based its cash flow projections to undertake impairment testing of goodwill:

Discount rate - The discount rate applied to the cash flow projections was 19.40% as at December 31, 2025 (2024: 24.20%). The discount rate used is before tax and reflects specific risks relating to the relevant unit.

Expected revenue – The revenue is based on the business strategy and management’s expectation for the market development.

The values assigned to the key assumptions are consistent with external information sources. The management believes that any reasonably possible change in any of the key assumptions on which the recoverable amount is based would not cause the cash-generating unit’s recoverable amount to drop lower than its carrying amount.

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15. OTHER INTANGIBLE ASSET

	Software RMB	Patent RMB	License RMB	Total RMB
December 31, 2024				
Cost at January 1, 2024, net of accumulated amortization	10,232	48,089	27,125	85,446
Additions	1,403	-	-	1,403
Amortization provided during the year (note 6)	(2,100)	(7,251)	(1,500)	(10,851)
At December 31, 2024	9,535	40,838	25,625	75,998
At December 31, 2024:				
Cost	18,728	93,050	30,000	141,778
Accumulated amortization	(9,193)	(52,212)	(4,375)	(65,780)
Net carrying amount	9,535	40,838	25,625	75,998
December 31, 2025				
Cost at January 1, 2025, net of accumulated amortization	9,535	40,838	25,625	75,998
Amortization provided during the year (note 6)	(1,262)	(7,300)	(1,500)	(10,062)
At December 31, 2025	8,273	33,538	24,125	65,936
At December 31, 2025:				
Cost	18,728	93,050	30,000	141,778
Accumulated amortization	(10,455)	(59,512)	(5,875)	(75,842)
Net carrying amount	8,273	33,538	24,125	65,936
Net carrying amount in US\$	1,183	4,796	3,450	9,429

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16. INVESTMENT IN A JOINT VENTURE

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Share of net assets	32,717	33,030	4,723

Particulars of the Group’s principal joint venture are as follows:

Name	Place of registration and business	Registered share capital RMB	Percentage of ownership interest	Principal activities
Suzhou Ascentage Harvest Venture Capital LLP* (“Ascentage Harvest”)	PRC	360,000	33.42%**	Investment in Biotechnology companies

The above investment is indirectly held by the Company.

* The English name of the company registered in the PRC represents the best efforts made by the management of the Company in directly translating the Chinese name of this Company as no English name has been registered.

** The Group holds two of three representatives in the committee that directs the relevant activities of Ascentage Harvest. As a result, the Group has significant influence over the financial and operating policy decisions of Ascentage Harvest.

The following table illustrates the summarized financial information of the Group’s joint venture:

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Share of the joint venture’s (loss)/gain for the year	(281)	314	45
Share of the joint venture’s total comprehensive (loss)/gain for the year	(281)	314	45
Aggregate carrying amount of the Group’s investment in the joint venture	32,717	33,030	4,723

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17. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Listed equity investments, at fair value	1,141	-	-
Other unlisted investments, at fair value	-	4,000	572
Total	1,141	4,000	572

The above listed equity investments were classified as financial assets at fair value through profit or loss as they were held for trading.

The above unlisted investments were classified as financial assets at fair value through profit or loss as they represent investments in non-trading equity instruments and have not been designated as financial assets at fair value through other comprehensive income.

18. DEFERRED TAX

The movements in deferred tax liabilities and assets during the reporting period are as follows:

Deferred tax liabilities

	Fair value adjustments arising from acquisition of a subsidiary	Right-of-use assets	Total
	RMB	RMB	RMB
At January 1, 2024	10,549	5,413	15,962
Deferred tax (credited)/charged to the statement of profit or loss during the year (note 9)	(5,181)	1,300	(3,881)
Deferred tax liabilities at December 31, 2024 and January 1, 2025	5,368	6,713	12,081
Deferred tax charged/(credited) to the statement of profit or loss during the year (note 9)	1,975	(1,241)	734
Deferred tax liabilities at December 31, 2025	7,343	5,472	12,815
Deferred tax liabilities at December 31, 2025 in US\$	1,051	782	1,833

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18. DEFERRED TAX (continued)

Deferred tax assets

	Contract liabilities RMB	Lease liabilities RMB	Donation expenses RMB	Losses Available for Offsetting Against Future Taxable profits RMB	Total RMB
At January 1, 2024	43,440	5,413	-	16,402	65,255
Deferred tax (credited)/charged to the statement of profit or loss during the year (note 11)	(5,623)	1,300	2,896	(12,879)	(14,306)
Deferred tax assets at December 31, 2024 and January 1, 2025	37,817	6,713	2,896	3,523	50,949
Deferred tax (credited)/charged to the statement of profit or loss during the year (note 11)	(12,582)	(1,241)	(1,204)	8,850	(6,177)
Deferred tax assets at December 31, 2025	25,235	5,472	1,692	12,373	44,772
Deferred tax assets at December 31, 2025 in US\$	3,609	782	242	1,769	6,402

For presentation purposes, certain deferred tax assets and liabilities have been offset in the statements of financial position. The following is an analysis of the deferred tax balances of the Group for financial reporting purposes:

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Deferred tax offset in the consolidated statements of financial position	6,713	12,815	1,833
Net deferred tax assets recognized in the consolidated statements of financial position	44,236	31,957	4,570
Net deferred tax liability recognized in the consolidated statements of financial position	5,368	-	-

As of December 31, 2024 and 2025, the Group has tax losses arising in Chinese mainland of RMB2,963,587 and RMB3,047,076 (US\$435,726), respectively, that will expire from 2026 to 2035 for offsetting against future taxable profits. The Group has tax losses arising in other jurisdictions of RMB1,438,160 and RMB2,250,477 (US\$321,814), mainly from the United States that are available indefinitely for offsetting against up to 80% of future taxable profits of the company in which the losses arose.

As of December 31, 2024 and 2025, the Group has deductible temporary differences of RMB828,668 and RMB1,000,310 (US\$143,042), respectively. The Group has the tax credits of RMB120,606 and RMB158,931 (US\$22,727), mainly from the United States that will expire between 2039 and 2045 if not utilized.

The deferred tax assets have not been recognized in respect of above tax losses, deductible temporary differences and tax credits as they have arisen in entities that have been loss-making and it is not anticipated there will be sufficient taxable income in the foreseeable future to utilize these items.

As of December 31, 2024 and 2025, there was no unrecognized deferred tax liability for taxes that would be payable on the unremitted earnings of the Group's subsidiaries or joint ventures in the Chinese mainland as these enterprises are still in accumulative losses status.

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18. DEFERRED TAX (continued)

Deferred tax assets (continued)

As of December 31, 2024 and 2025, the Company has uncertain tax position amounts of RMB23,665 and RMB37,901 (US\$5,420), respectively, of which nil and nil are presented on a net basis against the deferred tax assets related to tax loss carry forwards on the consolidated balance sheets. As of December 31, 2024 and 2025, the uncertain tax position amounts of RMB23,665 and nil (US nil), respectively, if ultimately recognized, will impact the effective tax rate.

For the years ended December 31, 2023, 2024 and 2025, the Company did not record any interest expense and penalty accrued in relation to the uncertain tax position in income tax expenses.

19. OTHER NON-CURRENT ASSETS

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Contract acquisition costs	30,529	29,851	4,269
Value added tax recoverable	26,034	-	-
Deposit	2,439	690	99
Prepayment for property, plant and equipment	301	184	26
Total	59,303	30,725	4,394

20. INVENTORIES

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Work in progress	2,736	25,371	3,628
Finished goods	3,861	7,427	1,062
Less: Provision	-	(4,180)	(598)
Total	6,597	28,618	4,092

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21. TRADE RECEIVABLES, NET

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Trade receivables, net	83,143	252,938	36,170

The Group’s trading terms with its customers are mainly on credit. The credit period is generally 45 to 120 days. Each customer has a maximum credit limit. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimize credit risk. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

An aging analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Within 45 days	54,484	252,938	36,170
45 to 120 days	28,659	-	-
Total	83,143	252,938	36,170

An impairment analysis is performed at each reporting date. The Group has applied the simplified approach to provide for ECLs prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. The directors of the Company are of the opinion that the ECL in respect of the balance of trade receivables is minimal. No loss allowance for impairment of trade receivables is provided as at December 31, 2025 (2024: nil).

22. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Prepayments for clinical trial expenses	71,050	100,769	14,410
Prepaid listing expense	22,465	-	-
Value added tax recoverable	9,794	46,748	6,685
Other receivables	6,137	1,455	208
Deposits	5,367	2,159	309
Prepayment for treasury share purchase fees	4,754	8,798	1,258
Other prepayments	3,644	32,603	4,662
Total	123,211	192,532	27,532

The carrying amounts of financial assets included in prepayments, other receivables and other assets approximate to their fair values.

The financial assets included in the above balances relate to receivables for which there was no recent history of default or past due amounts. As at December 31, 2024 and 2025, the loss allowance was assessed to be minimal.

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23. CASH AND BANK BALANCES

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Cash and cash equivalents as stated in the consolidated statements of cash flows	893,100	1,195,784	170,995
Restricted cash	24,633	5,685	812
Time deposits with original maturity of more than three months	343,478	1,268,616	181,410
Cash and bank balances as stated in the consolidated statements of financial position	1,261,211	2,470,085	353,217
Denominated in:			
RMB	298,922	205,783	29,426
US\$	947,012	2,257,307	322,791
HK\$	13,812	3,827	547
Others	1,465	3,168	453
Total	1,261,211	2,470,085	353,217

At the end of the reporting period, the cash and bank balances of the Group denominated in RMB amounted to RMB205,783 (US\$29,426) (2024: RMB298,922). The RMB is not freely convertible into other currencies, however, under Chinese mainland’s Foreign Exchange Control Regulations and Administration of Settlement, and Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorized to conduct foreign exchange business.

Cash at banks earn interest at floating rates based on daily bank deposit rates. Time deposits with original maturity of more than three months earn interest at fixed interest rates for varying periods of between two years and three years. The bank balances are deposited with creditworthy banks with no recent history of default.

24. TRADE PAYABLES

An aging analysis of the trade payables as at the end of each reporting period, based on the invoice date, is as follows:

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Within 1 month	72,506	91,119	13,030
1 to 3 months	6,288	3,648	522
3 to 6 months	13,172	11,973	1,712
Total	91,966	106,740	15,264

The trade payables are non-interest-bearing and are normally settled in less than six months.

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25. OTHER PAYABLES AND ACCRUALS

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Accrued promotion expenses	67,009	121,545	17,381
Payroll payables	61,848	78,423	11,214
Payables for construction cost	35,381	5,888	842
Long-term payables-current portion (note 36)	29,344	8,340	1,194
Other non-current liabilities-current portion (note 36)	-	1,968	281
Other payables	23,442	21,493	3,073
Government subsidy	16,600	22,600	3,232
Tax payables other than income tax	9,627	13,700	1,959
Other accrued expenses	14,847	2,709	387
Total	258,098	276,666	39,563

Other payables are non-interest-bearing.

26. CONTRACT LIABILITIES

Details of contract liabilities as at December 31, 2024 and 2025 are as follows:

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
<i>Short-term advances recognized from customers</i>			
Commercialization rights income	37,485	37,485	5,360
<i>Long-term advances recognized from customers</i>			
Commercialization rights income	248,460	210,224	30,062
Total	285,945	247,709	35,422

Contract liabilities include long-term and short-term advances related to commercialization rights.

In July 2021, the Group entered into an agreement with Innovent Biologics (Suzhou) Co., Ltd (“Innovent”). Under the agreement, the Group owns all intellectual property generated in connection with the development and commercialization of HQP1351. Innovent was granted the commercialization rights of HQP1351 in China and should make a non-refundable payment and milestone payments for such rights to the Group, which are recorded under contract liabilities and recognized as revenue over time during the commercialization period.

In accordance with the agreement, the Group recognized RMB349,523 (US\$49,981) in aggregate as contract liabilities from contract inception through December 31, 2025 (2024: RMB349,523). The Group recognized RMB37,485 (US\$5,360) as revenue during the year ended December 31, 2025 (2024: RMB37,485; 2023: RMB26,049). Milestone payments are recognized as the transaction price when the Group can conclude that it is highly probable that there will not be a subsequent reversal of a significant amount of revenue.

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27. INTEREST-BEARING BANK AND OTHER BORROWINGS

2024

	Effective interest rate per annum (%)	Maturity	RMB
Current			
Short-term borrowing	2.60-2.70 or 1 year LPR-0.30 to 0.75	2025	290,000
	1 year LPR-0.15 to 0.65 or 1 year LPR+0.65 to 0.85	2025	213,170
Current portion of long-term bank loans – unsecured	2.80 - 4.55	2025	255,000
Current portion of long-term bank loans – secured*	5 year LPR-0.85	2025	11,453
Lease liabilities (note 13(b))	4.00 - 4.35	2025	9,439
Total – current			779,062
Non-current			
	1 year LPR-0.45 to 0.65 or 1 year LPR+0.70 to 0.85	2026 - 2028	203,100
Bank loans – unsecured	2.80-4.50	2026 - 2027	77,250
Bank loans – secured*	5 year LPR-0.85	2026 - 2038	588,292
Lease liabilities (note 13(b))	4.00 - 4.35	2026 - 2028	20,793
Total – non-current			889,435
Total			1,668,497

2025

	Effective interest rate per annum (%)	Maturity	RMB	US\$
Current				
Short-term borrowing	2.11-2.50 or 1 year LPR-0.60 to 0.89	2026	1,040,000	148,718
Current portion of long term bank loans – unsecured	2.80	2026	2,500	358
Current portion of long term bank loans – unsecured	1 year LPR-0.45 to 0.75	2026	156,200	22,336
Current portion of long-term bank loans – secured*	5 year LPR-0.85	2026	16,498	2,359
Lease liabilities (note 13(b))	4.00 - 4.35	2026	7,283	1,041
Total – current			1,222,481	174,812
Non-current				
Bank loans – unsecured	1 year LPR-0.45 to 0.75	2027 – 2028	114,900	16,431
Bank loans – unsecured	2.80	2027	43,750	6,256
Bank loans – secured*	5 year LPR-0.85	2027 – 2038	583,675	83,464
Lease liabilities (note 13(b))	4.00 - 4.35	2027 – 2028	14,913	2,133
Total – non-current			757,238	108,284
Total			1,979,719	283,096

Note: LPR represents the Loan Prime Rate.

* The bank loans amounting to RMB600,173 (US\$85,823) as at December 31, 2025 were secured by the pledge of the Group’s buildings with a net carrying amount of RMB676,985 (US\$96,808) and right-of-use assets with a net carrying amount of RMB25,338 (US\$3,623) as at December 31, 2025. Such loans were also guaranteed by two of the Group’s subsidiaries.

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27. INTEREST-BEARING BANK AND OTHER BORROWINGS (continued)

The bank loans amounting to RMB599,745 as at December 31, 2024 were secured by the pledge of the Group’s buildings with a net carrying amount of RMB731,282 and right-of-use assets with a net carrying amount of RMB26,468 as at December 31, 2024. Such loans were also guaranteed by two of the Group’s subsidiaries.

The unsecured bank loans amounting to RMB140,000 (US\$20,020) (2024: RMB278,070) were guaranteed by the Group’s subsidiaries as at December 31, 2025.

The carrying amounts of borrowings are all denominated in RMB. The weighted average interest rate for the outstanding short-term bank loans as of December 31, 2024 and 2025, was 2.63% and 2.18%, respectively.

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
Analyzed into:			
Within one year	779,062	1,222,481	174,812
In the second year	242,473	160,201	22,908
In the third to fifth years, inclusive	159,355	140,100	20,034
Beyond five years	487,607	456,937	65,342
Total	1,668,497	1,979,719	283,096

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28. DEFERRED INCOME

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Government grants	27,500	6,500	929

The movements in government grants during the reporting period are as follows:

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
At beginning of the year	36,360	27,500	3,932
Received during the year	7,740	1,000	143
Portion classified as current liabilities (note 25)	(16,600)	(22,000)	(3,146)
At end of the year	27,500	6,500	929

29. SHARE CAPITAL AND TREASURY SHARES

Issued and fully paid

	As at December 31, 2023		
	Number of shares in issue	Share capital US\$	RMB equivalent RMB
Ordinary shares of US\$0.0001 each	290,196,560	27	197

	As at December 31, 2024		
	Number of shares in issue	Share capital US\$	RMB equivalent RMB
Ordinary shares of US\$0.0001 each	315,224,993	29	214

	As at December 31, 2025		
	Number of shares in issue	Share capital US\$	RMB equivalent RMB
Ordinary shares of US\$0.0001 each	373,321,692	37	256

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29. SHARE CAPITAL AND TREASURY SHARES (continued)

Movements in the issued share capital and treasury shares from January 1, 2023 to December 31, 2025 were as follows:

	Number of shares	Share capital RMB	Treasury shares RMB	Total RMB
At January 1, 2023	265,185,950	180	(26,552)	(26,372)
Issue of ordinary shares (a)	22,500,000	15	-	15
Issue of shares under the Pre-IPO share option scheme (b)	911,062	1	-	1
Issue of shares under the 2021 RSU scheme (c)	71,034	-	-	-
Equity-settled bonus (d)	1,528,514	1	1	2
Repurchase of ordinary shares (e)	-	-	(5,923)	(5,923)
Vesting of RSUs (f)	-	-	11,123	11,123
At December 31, 2023 and January 1, 2024	290,196,560	197	(21,351)	(21,154)
Issue of ordinary shares (g)	24,307,322	17	-	17
Issue of shares under the Pre-IPO share option scheme (h)	656,077	-	-	-
Issue of shares under the 2021 RSU scheme (i)	65,034	-	-	-
Equity-settled bonus (j)	-	-	8,631	8,631
Repurchase of ordinary shares (k)	-	-	(1,959)	(1,959)
Vesting of RSUs (l)	-	-	14,671	14,671
At December 31, 2024 and January 1, 2025	315,224,993	214	(8)	206
Issue of ordinary shares (m)	55,040,576	40	-	40
Issue of shares under the Pre-IPO share option scheme (n)	455,263	-	-	-
Issue of shares under the 2021 RSU scheme and 2022 RSU scheme (o)	1,008,253	2	-	2
Equity-settled bonus (p)	1,592,607	-	-	-
Repurchase of ordinary shares (q)	-	-	(3,590)	(3,590)
Vesting of RSUs (r)	-	-	637	637
At December 31, 2025	373,321,692	256	(2,961)	(2,705)
At December 31, 2025 in US\$	373,321,692	37	(423)	(386)

- (a) In connection with the share placement, 22,500,000 placing shares of the Company were issued and allotted at a price of HK\$24.45 per share on February 1, 2023, and an amount of RMB15 was credited as share capital.
- (b) During the year ended December 31, 2023, the Company issued ordinary shares with respect to the share options under the pre-IPO share option scheme exercised by certain grantees of the Company before December 31, 2023 to those grantees. In connection with the exercised share options, 911,062 new shares of the Company were issued with a weighted average exercise price of HK\$0.01, and an amount of RMB1 was credited as share capital.
- (c) In June 2023, the Company issued ordinary shares with respect to the RSUs under the 2021 RSU Scheme exercised by certain selected persons of the Company before December 31, 2023 to those selected persons. In connection with the exercised RSUs, 71,034 new shares of the Company were issued, and an amount of RMB0.05 was credited as share capital.
- (d) In June 2023, 1,528,514 ordinary shares and 1,237,884 treasury shares, being underlying shares of the RSUs granted under the 2021 RSU scheme and the 2018 RSU scheme, were allotted to the employees to settle the bonus due to employees, and amounts of RMB1 and RMB1 were credited as share capital and treasury shares, respectively.
- (e) In November 2023, the Company instructed the trustee to purchase 250,000 of its shares on the Hong Kong Stock Exchange at a total consideration of RMB5,923 for the purpose of the 2022 RSU scheme.
- (f) In connection with the exercise of RSUs granted under the 2018 and 2022 RSU Scheme, 1,069,461 treasury shares were allotted to the employees during the year ended December 31, 2023.

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29. SHARE CAPITAL AND TREASURY SHARES (continued)

- (g) In connection with the subscription of shares, 24,307,322 placing shares of the Company were issued and allotted at a price of HK\$24.10 per share on June 20, 2024, and an amount of RMB17 was credited as share capital.
- (h) During the year ended December 31, 2024, the Company issued ordinary shares with respect to the share options under the Pre-IPO share option scheme exercised by certain grantees of the Company. In connection with the exercised share options, 656,077 new shares of the Company were issued with a weighted average exercise price of HK\$0.01, and an amount of RMB0.5 was credited as share capital.
- (i) In June 2024, the Company issued ordinary shares with respect to the RSUs under the 2021 RSU Scheme exercised by certain selected persons of the Company before December 31, 2024 to those selected persons. In connection with the exercised RSUs, 65,034 new shares of the Company were issued, and an amount of RMB0.05 was credited as share capital.
- (j) In September 2024, 397,949 treasury shares and 2,081,399 treasury shares, being underlying shares of the RSUs granted under the 2022 RSU scheme and the 2018 RSU scheme, were allotted to the employees to settle the bonus due to employees, and amounts of RMB8,630 and RMB1.4 were both credited as treasury shares.
- (k) In February 2024, the Company instructed the trustee to purchase 100,000 of its shares on the Hong Kong Stock Exchange at a total consideration of RMB1,959 for the purpose of the 2022 RSU Scheme.
- (l) In connection with the vesting of RSUs granted under the 2018 and 2022 RSU Schemes, 939,687 treasury shares were allotted to the employees during the year ended December 31, 2024.
- (m) In connection with the subscription of shares, 7,325,000 ADS (represents 29,300,000 of the Company’s ordinary shares) were offered at a price of US\$17.25 per ADS on January 23, 2025, followed by an additional 935,144 ADS (represents 3,740,576 of the Company’s ordinary shares) were offered at the same price on February 13, 2025, and 22,000,000 placing shares of the Company were issued and allotted at a price of HK\$68.6 per share on July 17, 2025, amounts of RMB40 (US\$6) was credited as share capital.
- (n) During the year ended December 31, 2025, the Company issued ordinary shares with respect to the share options under the Pre-IPO share option scheme exercised by certain grantees of the Company. In connection with the exercised share options, 455,263 new shares of the Company were issued with a weighted average exercise price of HK\$0.01, and an amount of RMB0.3 (US\$0.04) was credited as share capital.
- (o) During June to September 2025, the Company issued ordinary shares with respect to the restricted share units under the 2021 and 2022 RSU Scheme exercised by certain selected persons of the Company before December 31, 2025 to those selected persons. In connection with the exercised restricted share units, 1,008,253 new shares of the Company were issued, and an amount of RMB0.7 (US\$0.1) was credited as share capital.
- (p) In June 2025, 775,685 ordinary shares and 816,922 ordinary shares, being underlying shares of the restricted share units granted under the 2021 RSU scheme and the 2022 RSU scheme, were allotted to the employees to settle the bonus due to employees, and amounts of RMB0.5 (US\$0.07) and RMB0.6 (US\$0.09) credited as share capital.
- (q) In April 2025, the Company instructed the trustee to purchase 100,000 of its shares on the Hong Kong Stock Exchange at a total consideration of RMB3,590 (US\$513) for the purpose of the 2022 RSU scheme.
- (r) In connection with the vesting of restricted share units granted under the 2022 RSU Scheme, 17,925 treasury shares were allotted to the employees during the year ended December 31, 2025.

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30. RESERVES

The amounts of the Group’s reserves and the movements therein for the current and prior years are presented in the consolidated statements of changes in equity.

In connection with the post-IPO share option scheme, the 2021 RSU Scheme, and 2022 RSU Scheme, expenses amounting to RMB20,874 (US\$2,985) (2024: RMB20,924; 2023: RMB31,503) were recognized and contributed to capital and reserves during the year ended December 31, 2025.

Upon the exercise of the Pre-IPO share option scheme and vesting of restricted share units granted under the 2021 RSU Scheme, and 2022 RSU Scheme, RMB33,000 (US\$4,719) (2024: RMB19,333; 2023: RMB32,593) was credited to share premium, and RMB33,635 (US\$4,810)(2024: RMB33,998; 2023: RMB43,709) was transferred out from capital and reserves during the year ended December 31, 2025.

Under PRC laws and regulations, there are restrictions on the Company’s PRC subsidiaries with respect to transferring certain of their net assets to the Company either in the form of dividends, loans, or advances. Amounts of net assets restricted include paid in capital and reserve funds of the Company’s PRC subsidiaries, totaling RMB3,033,545 (US\$433,791) and RMB2,702,519 as at December 31, 2025 and 2024, respectively. See note 41 for the statement of financial position of the Company.

In connection with the equity-settled bonus, the Company settled the bonus of RMB58,869 (US\$8,418) (2024: RMB49,350) by issuing 1,592,607 ordinary shares (2024: 2,479,348 treasury shares) at a price of HK\$40.05 (2024: HK\$21.95) to employees, among which, RMB58,868 (US\$8,418) (2024: RMB40,719) was credited to share premium.

31. SHARE-BASED PAYMENTS

(a) Share option scheme

The pre-IPO share option scheme

In July 2018, the Company adopted the pre-IPO share option scheme for the purpose of providing incentives and rewards to eligible participants who have contributed or will contribute to the Group. Eligible participants of the pre-IPO share option scheme may include any substantial shareholder, existing or incoming employees, directors (including executive directors, non-executive directors and independent non-executive directors) and officers, or any other service providers of any member of the Group who the board of directors consider, in its sole discretion, have contributed or will contribute to the Group. The pre-IPO share option scheme was terminated but continues to govern the terms and conditions of the outstanding awards previously granted under the Company’s pre-IPO share option scheme.

The maximum number of shares which may be issued upon the exercise of all pre-IPO share options is 12,307,533. The exercise price for each share under the pre-IPO share options was HK\$0.01.

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31. SHARE-BASED PAYMENTS (continued)

(a) Share option scheme (continued)

The following share options were outstanding under the Pre-IPO share option scheme during the year:

	2024		2025	
	Exercise price HK\$ per share	Number of options	Exercise price HK\$ per share	Number of options
Outstanding as of January 1	0.01	3,263,648	0.01	2,607,571
Forfeited during the year	-	-	0.01	(81)
Exercised during the year	0.01	(656,077)	0.01	(455,263)
Outstanding as of December 31	0.01	2,607,571	0.01	2,152,227

The number of share options exercisable was 2,152,227 as at December 31, 2025 (2024: 2,607,571).

The weighted average share price at the date of exercise for share options exercised during the year ended December 31, 2025 was HK\$58.54 per share (2024: HK\$34.03 per share, 2023: HK\$22.98 per share).

The exercise prices and exercise periods of the share options outstanding as at the end of the reporting period are as follows:

2024 Number of options	Exercise price HK\$ per share	Exercise period
2,360,420	0.01	Aug 15, 2018-Aug 15, 2028
232,719	0.01	May 15, 2019-May 15, 2029
14,432	0.01	Sept 16, 2019-Sept 16, 2029
2,607,571		

2025 Number of options	Exercise price HK\$ per share	Exercise period
1,983,383	0.01	Aug 15, 2018-Aug 15, 2028
159,712	0.01	May 15, 2019-May 15, 2029
9,132	0.01	Sept 16, 2019-Sept 16, 2029
2,152,227		

The Group did not grant any new share options under the Pre-IPO share option scheme during the year ended December 31, 2025 (2024: Nil). As the share options have been fully unlocked in 2023, the Group has not recognized any share option expense during the year ended December 31, 2025 (2024: Nil, 2023: RMB3,750).

The exercise in full of the outstanding share options would, under the present capital structure of the Company, result in the issue of 2,152,227 additional ordinary shares of the Company and additional share capital and share premium of US\$4,957, equivalent to RMB34,662 (before issue expenses), transferred from capital and other reserves.

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31. SHARE-BASED PAYMENTS (continued)

(a) Share option scheme (continued)

The post-IPO share option scheme

In September 2019, the Company adopted the post-IPO share option scheme for the purpose of providing incentives and rewards to eligible participants who have contributed or will contribute to the Group. Eligible participants of the post-IPO share option scheme include (a) any executive director of, manager of, or other employee holding an executive, managerial, supervisory or similar position in any member of the Group, any full-time or part-time employee, or a person for the time being seconded to work full-time or part-time for any member of the Group; (b) a director or proposed director (including an independent non-executive director) of any member of the Group; (c) any substantial shareholder of any member of the Group; (d) a customer, consultant, business or joint venture partner, franchisee, contractor, agent or representative of, a supplier of goods or services to, a person or entity that provides design, research, development or other support or any advisory, consultancy, professional or other services to any member of the Group; and (e) an associate of any of the persons referred to in paragraphs (a) to (c) above.

In April 2025, the Company amended the post-IPO share option scheme. Under the amendments, eligible participants were restricted to (i) Employee Participants (as defined under former paragraphs (a) and (b)) and (ii) Service Providers, and the categories previously set out in former paragraphs (c), (d) and (e) were eliminated. In addition, the maximum number of shares which may be issued upon the exercise of all Post-IPO share options was reduced from 20,707,462 to 14,907,462.

Under the post-IPO share option scheme, the maximum number of shares issuable upon the exercise of all options granted under this and other Group plans shall not exceed 10% of the Company’s issued share capital as of the listing date (including any outstanding, cancelled, lapsed, or unexercised options). The Company may, with separate shareholder approval, grant options exceeding this limit, provided that any excess is granted only to eligible participants. The aggregate number of shares subject to options granted under the Post-IPO Share Option Scheme and other Group plans shall not exceed 30% of the Group’s issued share capital at the time of grant.

Subject to any restriction contained in the post-IPO share option scheme, an option may be exercised in accordance with the terms of the post-IPO share option scheme.

On November 26, 2025, the Company granted options to 33 grantees to subscribe for an aggregate of 633,243 shares under the post-IPO share option scheme. Subject to the terms and conditions as set out in the Post-IPO share option scheme, 486,868 shares granted to 25 grantees are vested in the portions of 25%, 25%, 25% and 25% on the first, second, third and fourth anniversaries of the grant date of the options, and the remaining options granted to eight grantees in respect of 146,375 shares are vested in the portion of 8.33% monthly on the 26th of each month over an 11-month period starting from November 26, 2025, with the remaining 8.37% to be vested on October 26, 2026. The exercise price for each share under the post-IPO share options is HK\$63.35.

There are no cash settlement alternatives. The Group does not have a past practice of cash settlement for these share options. The Group accounts for the scheme as an equity-settled plan. Share options do not confer rights on the holders to dividends or to vote at shareholders’ meetings.

The following share options were outstanding under the post-IPO share option scheme during the year:

	2025	
	Exercise price HK\$ per share	Number of options
Outstanding as of January 1	63.35	-
Granted during the year	63.35	633,243
Exercised during the year	63.35	-
Outstanding as of December 31	63.35	633,243

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31. SHARE-BASED PAYMENTS (continued)

(a) Share option scheme (continued)

The exercise prices and exercise periods of the share options outstanding as at the end of the reporting period are as follows:

2025 Number of options	Exercise price HK\$ per share	Exercise period
633,243	63.35	Nov 26, 2025–Nov 26, 2035

The Group granted 633,243 new shares options under the Post-IPO Scheme during the year ended December 31, 2025 (2024: Nil), and recognized share option expense of RMB2,420 (US\$346) during the year ended December 31, 2025.

The exercise in full of the outstanding share options would, under the present capital structure of the Company, result in the issue of 633,243 additional Ordinary Shares of the Company and additional share capital and share premium of US\$2,902 equivalent to RMB20,294 (before issue expenses) transferred from capital and other reserves.

The fair value of the share options granted was estimated as at the grant date by using the binary tree option pricing model. The following table lists the key inputs to the fair value model used:

At grant dates

Expected volatility	49.65%
Risk-free interest rate%	3.09%
Expected life of options (year)	10.00
Weighted average share price (HKD per share)	34.98

(b) RSUs granted to employees

The 2018 RSU Scheme

On July 6, 2018, the Company approved and adopted the 2018 RSU Scheme. The purpose of the 2018 RSU scheme is to incentivize the existing and incoming directors, senior management and employees for their contribution to the Company, and to attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of the Company. Unless otherwise cancelled or amended, the 2018 RSU Scheme will remain in force for 10 years from the date of adoption.

The maximum number of RSUs that may be granted under the 2018 RSU Scheme in aggregate (excluding RSUs that have lapsed or been cancelled in accordance with the rules of the 2018 RSU Scheme) shall be 5,274,657 ordinary shares.

On September 14, 2020, pursuant to the 2018 RSU Scheme, 2,590,592 RSUs were granted to 50 selected persons, who are employees of the Company. The RSUs granted would vest on the third month from the grant date, and in equal tranches over the remaining years of the total vesting period as three years, on condition that employees remain in service without any performance requirements.

The fair value of each RSU under the 2018 RSU Scheme at the grant date was determined by reference to the fair value of the ordinary shares of the Company issued to its shareholders, using the market approach.

The Group did not recognize share-base payment expense during the year ended December 31, 2025 (2024: Nil; 2023: RMB3,169).

As at December 31, 2023, all RSUs under the 2018 RSU Scheme had been exercised.

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31. SHARE-BASED PAYMENTS (continued)

(b) RSUs granted to employees (continued)

The 2021 RSU Scheme

On February 2, 2021, the Company approved and adopted the 2021 RSU Scheme. The purpose of the 2021 RSU scheme is to (i) incentivize the existing and incoming directors, senior management, and employees for their contribution to the Group; and (ii) attract, motivate, and retain skilled and experienced personnel to strive for the future development and expansion of the Group by providing them with the opportunity to own equity interests in the Company. Unless otherwise cancelled or amended, the 2021 RSU Scheme will remain in force for 10 years from the date of adoption.

The maximum number of RSUs that may be granted under the 2021 RSU Scheme in aggregate (excluding RSUs that have lapsed or been cancelled in accordance with the 2021 Scheme Rules) shall be 3,133,526 shares.

On April 30, 2025, the Company amended the 2021 RSU Scheme, thereby expanding the eligible participants by adding a service provider as a new category of eligible participants.

On May 17, 2021, pursuant to the 2021 RSU Scheme, 440,490 RSUs were granted to 34 selected persons, which include employees, senior management of the Group, and a director of the Company. Among the awards, 10,641 RSUs were granted to an independent non-executive director and 55,157 RSUs were granted to the Chief Commercial Officer. On July 23, 2021, 26,892 RSUs were granted to three independent non-executive directors of the Company. The RSUs granted were categorized in six types based on the vesting period and the proportion of shares that can be unlocked upon each of the vesting dates.

Details of the unlocking date are summarized as follows:

Type of eligible participants	Grant fair value HK\$ per share	% of conditional shares	Vesting date	% of vested conditional shares
1	43.80	100%	June 8, 2021-2024	35%, 15%, 25%, 25%
2	43.80	100%	June 8, 2021-2024	25%, 25%, 25%, 25%
3	43.80	100%	June 8, 2022–2025	35%, 15%, 25%, 25%
4	43.80	100%	April 30, 2022–2025	35%, 15%, 25%, 25%
5	43.80	100%	June 8, 2022–2025	25%, 25%, 25%, 25%
6	52.00	100%	June 8, 2022–2025	25%, 25%, 25%, 25%

On June 27, 2025, 48,439 RSUs were granted to 34 selected persons of the Commercialization Department.

Details of the unlocking date are summarized as follows:

Type of eligible participants	Grant fair value HK\$ per share	% of conditional shares	Vesting date	% of vested conditional shares
1	77.45	100%	June 27, 2025	100 %

As for the restricted shares granted to employees and senior management, the conditions for releasing the restrictions comprised two parts, namely the participants have not been terminated with or without cause on or before each relevant vesting date and the participants have obtained a score of B or above in the annual performance review prior to the applicable vesting date. The percentage of shares in respect of which the restrictions may be released depends on the achievement of those conditions. For the independent non-executive directors, the restricted shares would vest on condition that independent non-executive directors remain in service without any performance requirements.

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31. SHARE-BASED PAYMENTS (continued)

(b) RSUs granted to employees (continued)

The following restricted shares were outstanding under the 2021 RSU Scheme during the year:

	2024	2025
	Number of	Number of
	RSUs	RSUs
Outstanding as of January 1	108,998	41,552
Granted during the year	-	48,439
Forfeited during the year	(2,412)	-
Vested during the year	(65,034)	(89,991)
Outstanding as of December 31	<u>41,552</u>	<u>-</u>

The fair value of each RSUs under the 2021 RSU Scheme at the grant date was determined by reference to the fair value of the ordinary shares of the Company issued to its shareholders, using the market approach.

The weighted average share price at the date of exercise for RSUs exercised during the year was HK\$70.48 per share (2024 HK\$20.80 per share, 2023 HK\$19.96 per share).

The Company recognized a share-base payment expense of RMB3,604 (US\$515) during the year ended December 31, 2025 (2024: RMB856; 2023: RMB1,589).

The exercise in full of the outstanding RSUs would, under the present capital structure of the Company, result in additional share capital and share premium of HK\$1,894, equivalent to RMB1,712 (US\$245), transferred from capital and other reserves.

The 2022 RSU Scheme

On June 23, 2022, the Company approved and adopted the 2022 RSU Scheme. The purpose of the 2022 RSU scheme is to (i) incentivize the existing and incoming directors, senior management, and employees for their contribution to the Group; and (ii) attract, motivate, and retain skilled and experienced personnel to strive for the future development and expansion of the Group by providing them with the opportunity to own equity interests in the Company. Unless otherwise cancelled or amended, the 2022 RSU Scheme will remain in force for 10 years from the date of adoption.

The maximum number of RSUs that may be granted under the 2022 RSU Scheme in aggregate (excluding RSUs that have lapsed or been cancelled in accordance with the 2022 Scheme Rules) shall be 11,072,695 shares.

On April 30, 2025, the Company amended the 2022 RSU Scheme, thereby expanding the eligible participants by adding a service provider as a new category of eligible participants.

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31. SHARE-BASED PAYMENTS (continued)

(b) RSUs granted to employees (continued)

As for the restricted shares granted to employees and senior management under the 2022 RSU Scheme, the conditions for releasing the restrictions comprised two parts, namely the participants having not been terminated with or without cause on or before each relevant vesting date and the participants having obtained a score of B or above in the annual performance review prior to the applicable vesting date. The percentage of shares in respect of which the restrictions may be released depends on the achievement of those conditions.

Pursuant to the 2022 RSU Scheme, on June 23, 2022, the Company initially granted an aggregate of 1,634,426 RSUs under the 2022 RSU Scheme (the “2022 Awards”), representing 1,634,426 shares to a total of 80 selected persons, who are employees of the Group, among which 100,000 RSUs, representing 100,000 shares, were granted to Dr. Zhai Yifan (“Dr. Zhai”), who is the chief medical officer and a substantial shareholder of the Company. The RSUs granted were categorized in six types based on the vesting period and the proportion of shares that can be unlocked upon each vesting date.

Details of the unlocking date are summarized as follows:

Type of eligible participants	Grant fair value HK\$ per share	% of conditional shares	Vesting date	% of vested conditional shares
1	20.15	100%	June 8, 2021-2024	35%, 15%, 25%, 25%
2	20.15	100%	April 30, 2023–2026	25%, 25%, 25%, 25%
3	20.15	100%	June 8, 2023–2026	25%, 25%, 25%, 25%
4	20.15	100%	June 8, 2023–2024	40%, 60%
5	20.15	100%	June 8, 2023–2025	30%, 30%, 40%
6	20.15	100%	April 30, 2023–2026	23%, 69%, 6%, 2%

Pursuant to the 2022 RSU Scheme, on May 4, 2023, the Company granted 1,379,094 RSUs under the 2022 RSU Scheme, representing 1,379,094 shares to 172 selected persons (the “2022 Further Grant”), who are employees of the Group. The RSUs granted were categorized in two types based on the vesting period and the proportion of shares that can be unlocked upon each vesting date.

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31. SHARE-BASED PAYMENTS (continued)

(b) RSUs granted to employees (continued)

Details of the unlocking date are summarized as follows:

Type of eligible participants	Grant fair value HK\$ per share	% of conditional shares	Vesting date	% of vested conditional shares
1	21.8	100%	August 1, 2023–2024	40%, 60%
2	21.8	100%	August 1, 2023–2025	30%, 30%, 40%

Pursuant to the 2022 RSU Scheme, on September 2, 2024, the Company granted 777,006 RSUs under the 2022 RSU Scheme, representing 777,006 shares to 59 selected persons (the “2022 Further Grant”), who are employees of the Group. The RSUs granted were categorized in ten types based on the vesting period and the proportion of shares that can be unlocked upon each vesting date.

Details of the unlocking date are summarized as follows:

Type of eligible participants	Grant fair value HK\$ per share	% of conditional shares	Vesting date	% of vested conditional shares
1	33.95	100%	September 16, 2024	100%
2	33.95	100%	September 16, 2024-2025	75%, 25%
3	33.95	100%	September 16, 2024-2025	50%, 50%
4	33.95	100%	September 16, 2024-2026	30%, 30%, 40%
5	33.95	100%	September 16, 2024-2026	22.5%, 22.5%, 55%
6	33.95	100%	September 16, 2024-2026	50%, 25%, 25%
7	33.95	100%	September 16, 2024-2026	25%, 37%, 38%
8	33.95	100%	September 16, 2025	100%
9	33.95	100%	September 16, 2025-2026	40%, 60%
10	33.95	100%	September 16, 2025-2026	50%, 50%

Pursuant to the 2022 RSU Scheme, on November 26, 2025, the Company granted 1,177,256 RSUs under the 2022 RSU Scheme, representing 1,177,256 shares to 145 selected persons, who are employees of the Group, among which 143,363 RSUs, representing 143,363 shares, were granted to Dr. Yang Dajun (“Dr. Yang”), who is the chief executive officer of the Company. The RSUs granted were categorized in six types based on the vesting period and the proportion of shares that can be unlocked upon each vesting date.

Type of eligible participants	Grant fair value HK\$ per share	% of conditional shares	Vesting date	% of vested conditional shares
1	63.35	100%	November 26, 2026-2028	33.33%, 33.33%, 33.34%
2	63.35	100%	November 26, 2026-2029	25%, 25%, 25%, 25%

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31. SHARE-BASED PAYMENTS (continued)

(b) RSUs granted to employees (continued)

The following restricted shares were outstanding under the 2022 RSU Scheme during the year:

	2024 Number of RSUs	2025 Number of RSUs
Outstanding as of January 1	1,641,974	1,436,525
Granted during the year	777,006	1,177,256
Forfeited during the year	(42,768)	(132,302)
Vested during the year	(939,687)	(936,187)
Outstanding as of December 31	1,436,525	1,545,292

The fair value of each RSU under the 2022 RSU Scheme at the grant date was determined by reference to the fair value of the ordinary shares of the Company issued to its shareholders, using the market approach.

Under the 2022 RSU Scheme, the fair value of the RSUs granted during the year ended December 31, 2025 amounted to RMB68,327 (US\$9,771) (2024: RMB24,078, 2023: RMB27,063).

The weighted average share price at the date of exercise for RSUs exercised during the year through the treasury was HK\$20.14 per share (2024: HK\$19.24 per share, 2023: HK\$18.15 per share) and through the issuance was HK\$79.35 per share.

The Company recognized a share-base payment expense of RMB14,850 (US\$2,124) for the year ended December 31, 2025 (2024: RMB20,068, 2023: RMB22,995).

The exercise in full of the outstanding RSUs would, under the present capital structure of the Company, result in additional share capital and share premium of HK\$85,945, equivalent to RMB78,740 (US\$11,260), transferred from capital and other reserves.

There are no cash settlement alternatives. The Group does not have a past practice of cash settlement for these RSUs. The Group accounts for the scheme as an equity-settled plan.

32. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

a) Major non-cash transactions

- i. During the year ended December 31, 2025, the Company granted 633,243 options (2024: Nil, 2023: Nil) under the Post-IPO option scheme to 33 grantees.
- ii. During the year ended December 31, 2025, the Company issued 48,439 RSUs under the 2021 RSU scheme to 34 grantees and 1,177,256 RSUs under the 2022 RSU scheme to 145 grantees. During the year ended December 31, 2024, the Company granted nil RSUs under 2021RSU and granted 777,006 RSUs under the 2022 RSU scheme to 59 grantees. During the year ended December 31, 2023, the Company granted nil RSUs under 2021RSU and granted 1,379,094 RSUs under the 2022 RSU scheme to 172 grantees.
- iii. During the year ended December 31, 2025, the Company issued 1,592,607 newly issued shares to employees including 176,278 newly issued shares to Dr. Zhai as settlement of bonus of RMB58,869 (US\$8,418) (2024: RMB49,350, 2023: RMB55,468).
- iv. During the year ended December 31, 2025, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB5,047 (US\$722) (2024: RMB17,108, 2023: RMB16,194), and non-cash disposals of RMB2,675 (US\$382) and RMB3,360 (US\$480) (2024: RMB1,067 and RMB1,152, 2023: Nil and Nil), respectively, in respect of lease arrangements for buildings.
- v. As at December 31, 2025, 2024 and 2023, the Group had non-cash additions to intangible assets of nil, RMB1,403, and RMB805, respectively, and non-cash additions to property, plant and equipment of RMB 10,011 (US\$1,432), RMB9,424 and RMB26,823, respectively, included in other payables and accruals.

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32. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

b) Changes in liabilities arising from financing activities

	Accrued interest in other payables and accruals RMB	Bank and other loans RMB	Lease liabilities RMB
At January 1, 2023	383	1,775,505	17,222
Changes from financing cash flows	(91,027)	(2,591)	(10,766)
New leases	-	-	16,194
Interest expenses	91,690	-	1,321
Interest paid classified as financing cash flows	-	-	(1,321)
Effect of change in foreign exchange rates	-	-	31
At December 31, 2023	1,046	1,772,914	22,681
	Accrued interest in other payables and accruals RMB	Bank and other loans RMB	Lease liabilities RMB
At January 1, 2024	1,046	1,772,914	22,681
Changes from financing cash flows	(59,057)	(136,928)	(8,413)
New leases	-	-	17,108
Disposal	-	-	(1,152)
Interest expenses	59,276	2,279	1,498
Interest paid classified as financing cash flows	-	-	(1,498)
Effect of change in foreign exchange rates	-	-	8
At December 31, 2024	1,265	1,638,265	30,232
	Accrued interest in other payables and accruals RMB	Bank and other loans RMB	Lease liabilities RMB
At January 1, 2025	1,265	1,638,265	30,232
Changes from financing cash flows	(50,190)	316,980	(9,717)
New leases	-	-	5,047
Disposal	-	-	(3,360)
Interest expenses	49,534	2,278	1,118
Interest paid classified as financing cash flows	-	-	(1,118)
Effect of change in foreign exchange rates	-	-	(6)
At December 31, 2025	609	1,957,523	22,196
At December 31, 2025 in US\$	87	279,922	3,174

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32. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

c) Total cash outflow for leases

The total cash outflow for leases included in the statements of cash flows is as follows:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Within operating activities	181	238	329	47
Within financing activities	12,087	9,911	10,835	1,549
	<u>12,268</u>	<u>10,149</u>	<u>11,164</u>	<u>1,596</u>

33. COMMITMENTS

- a) As at December 31, 2025, the Group had capital commitments of RMB307 (US\$44) relating to furniture and equipment (2024: RMB4,366).
- b) The Group has no lease contracts that have not yet commenced as at December 31, 2025.
- c) The Group enters into business agreements with institutions to license intellectual property. The Group may be obligated to make future research and developmental milestone payments, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with the agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on the consolidated financial statements because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales has occurred, the corresponding amounts are recognized in the consolidated financial statements.

34. CONTINGENT LIABILITIES

The Group had no significant contingent liabilities as at the end of the reporting date.

35. PLEDGE OF ASSETS

Details of the Group’s assets pledged for the Group’s bank loans are included in note 27 to the consolidated financial statements.

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36. RELATED PARTY TRANSACTIONS

a) Apart from the transactions detailed elsewhere in this financial information, the Group had no transactions with related parties during the years ended December 31, 2023, 2024 and 2025.

b) Transaction with a related party

	For the years ended December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Dr. Zhai Yifan	-	29,533	4,223
Dr. Yang Dajun	-	3,933	562
	-	33,466	4,785

According to the HealthQuest Pharma Acquisition Agreement, a contingent consideration of RMB29,533 (US\$4,223) due to Dr. Zhai was recognized during the year ended December 31, 2025.

On 17 July 2025, the Company borrowed 22,000,000 ordinary shares of the Company from Dr. Yang to fulfil a placement to designated subscribers within the required timeline. The borrowed shares were returned to Dr. Yang on 29 July 2025 through the issuance of new shares, accompanied by a contractual borrowing cost payment of RMB 3,933, which was recorded as a reduction in equity in connection with such issuance.

c) Outstanding balance with a related party

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Other payables and accruals	29,344	10,308	1,474
Other non-current liabilities	-	6,374	911
Total for Dr. Zhai Yifan	29,344	16,682	2,385

In accordance with the acquisition agreement, payable to Dr. Zhai Yifan represented the contingent consideration related to the acquisition of Guangzhou HealthQuest Pharma Co., Ltd.

d) Compensation of key management personnel of the Group:

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Short term employee benefits and fees	20,118	19,059	59,283	8,477
Equity-settled share-based payment expenses	1,763	625	3,141	449
Post-employment benefits	986	977	711	102
Total	22,867	20,661	63,135	9,028

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37. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each reporting period are as follows:

2024

Financial assets

	Financial assets at fair value through profit or loss	Financial assets at amortized cost	Total
	RMB	RMB	RMB
Financial assets included in prepayments, other receivables and other assets	-	9,846	9,846
Cash and bank balances	-	1,261,211	1,261,211
Trade receivables	-	83,143	83,143
Financial assets at FVTPL	1,141	-	1,141
Financial assets included in other non-current assets	-	2,439	2,439
Total	1,141	1,356,639	1,357,780

Financial liabilities

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortized cost	Total
	RMB	RMB	RMB
Interest-bearing bank and other borrowings (current and non-current portions)	-	1,668,497	1,668,497
Trade payables	-	91,966	91,966
Financial liabilities included in other payables and accruals	-	103,014	103,014
Other non-current liabilities	-	6,274	6,274
Total	-	1,869,751	1,869,751

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37. FINANCIAL INSTRUMENTS BY CATEGORY (continued)

2025

Financial assets

	Financial assets at fair value through profit or loss RMB	Financial assets at amortized cost RMB	Total RMB	Total US\$
Financial assets included in prepayments, other receivables and other assets	-	3,609	3,609	516
Cash and bank balances	-	2,470,085	2,470,085	353,217
Trade receivables	-	252,938	252,938	36,170
Financial assets at FVTPL	4,000	-	4,000	572
Financial assets included in other non-current assets	-	690	690	99
Total	4,000	2,727,322	2,731,322	390,574

Financial liabilities

	Financial liabilities at fair value through profit or loss RMB	Financial liabilities at amortized cost RMB	Total RMB	Total US\$
Interest-bearing bank and other borrowings (current and non-current portions)	-	1,979,719	1,979,719	283,096
Trade payables	-	106,740	106,740	15,264
Financial liabilities included in other payables and accruals	1,968	138,482	140,450	20,084
Other non-current liabilities	6,374	5,657	12,031	1,720
Total	8,342	2,230,598	2,238,940	320,164

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38. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

The carrying amounts of the Group’s financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

	As at December 31,					
	Carrying amounts			Fair values		
	2024 RMB	2025 RMB	2025 US\$	2024 RMB	2025 RMB	2025 US\$
Financial assets						
Financial assets at FVTPL	1,141	4,000	572	1,141	4,000	572
Financial assets included in other non-current assets	2,439	690	99	2,311	624	89
Total	3,580	4,690	671	3,452	4,624	661
Financial liabilities						
Financial liabilities included in other payables and accruals	-	1,968	282	-	1,968	281
Other non-current liabilities	6,274	12,031	1,720	5,742	11,706	1,674
Non-current portion of interest-bearing bank and other borrowings (other than lease liabilities)	868,642	742,325	106,151	859,707	709,342	101,435
Total	874,916	756,324	108,153	865,449	723,016	103,390

Management has assessed that the fair values of cash and bank balances, trade receivables, financial assets included in prepayments, deposits and other receivables, trade payables, the current portion of long-term payables, the current portion of interest-bearing bank and other borrowings, financial liabilities included in other payables, and accruals approximate to their carrying amounts largely due to the short-term maturities of these instruments, or the interest rate being approximate to the discount rate of current market.

The Group’s finance department 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 each reporting date, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The directors review the results of the fair value measurement of financial instruments periodically for 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 following methods and assumptions were used to estimate the fair values:

The fair values of the financial assets and liabilities included in other non-current assets, and 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 Group’s own non-performance risk for other non-current assets, and interest-bearing bank and other borrowings as at December 31, 2025 was assessed to be insignificant.

The fair values of listed equity investments are based on quoted market prices. The fair value of the unlisted equity investments designated at fair value through profit or loss have been estimated using an asset-based valuation technique based on assumptions that are not supported by observable market prices or rates. The fair value measurement of these financial instruments may involve unobservable inputs. Fair value change resulting from changes in the unobservable inputs was not significant.

For Level 3 financial liabilities, the Group adopts the valuation techniques to determine the fair value. Valuation techniques include a discounted cash flow analysis. The fair value measurement of the financial instruments may involve unobservable inputs such as discount rate and possibility of payment. The Group periodically reviews all significant unobservable inputs and valuation adjustments used to measure the fair values of financial assets in Level 3.

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38. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (continued)

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair value

As at December 31, 2024

	Fair value measurement using			Total RMB
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB	RMB	RMB	
Financial assets at FVTPL	1,141	-	-	1,141

As at December 31, 2025

	Fair value measurement using			Total RMB	Total US\$
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)		
	RMB	RMB	RMB		
Financial assets at FVTPL	-	-	4,000	4,000	572

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38. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (continued)

Fair value hierarchy (continued)

Liabilities measured at fair value

As at December 31, 2025

	Fair value measurement using			Total RMB	Total US\$
	Quoted prices in active markets (Level 1) RMB	Significant observable inputs (Level 2) RMB	Significant Unobservable inputs (Level 3) RMB		
Financial liabilities included in other payables and accruals	-	-	1,968	1,968	281
Other non-current liabilities	-	-	6,374	6,374	911

During the years ended December 31, 2023, 2024 and 2025, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

39. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise cash and bank balances and interest-bearing bank and other borrowings. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as trade receivables and trade payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are interest rate risk, foreign currency risk, credit risk, liquidity risk, and equity price risk. The Directors review and agree on policies for managing each of these risks, and they are summarized below.

Interest rate risk

The Group’s exposure to the risk of changes in market interest rates relates primarily to the Group’s long-term debt obligations with floating interest rates.

The Group’s policy is to manage its interest cost using a mix of fixed and floating rate debts.

As at December 31, 2025, the total interest-bearing bank borrowings of RMB1,911,273 (US\$273,308) (2024: RMB1,116,015) of the Group were with floating interest rates denominated in RMB.

The following table demonstrates the sensitivity to a reasonably possible change in the RMB interest rate, with all other variables held constant, of the Group’s loss before tax through the impact on floating rate borrowings. This analysis does not include the effect of interest capitalized.

	Increase/ (decrease) in basis points	Increase/ (decrease) in loss before tax RMB
2024		
RMB	100	11,160
RMB	(100)	(11,160)
2025		
RMB	100	19,113
RMB	(100)	(19,113)

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39. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from sales or purchases by operating units and investing and financing activities in currencies other than the units’ functional currencies.

The following table demonstrates the sensitivity as at the end of each reporting period to a reasonably possible change in the US\$ and HK\$ exchange rates, with all other variables held constant, of the Group’s loss before tax and in other comprehensive income (without tax) due to changes in the fair values of monetary assets and liabilities.

	Increase/ (decrease) in foreign currency rate %	Increase/ (decrease) in loss before tax RMB	Increase/ (decrease) in other comprehensive income (without tax) RMB
December 31, 2024			
If RMB weakens against US\$	5	(44)	56,796
If RMB strengthens against US\$	(5)	44	(56,796)
December 31, 2025			
If RMB weakens against US\$	5	(65)	124,210
If RMB strengthens against US\$	(5)	65	(124,210)

Credit risk

The Group trades only with recognized and creditworthy third parties. Concentrations of credit risk are managed by the customer. At the end of the reporting period, the Group had certain concentrations of credit risk as 68% (2024: 73%) and 91% (2024: 96%) of the Group’s trade receivables were due from the Group’s largest customer, respectively. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis, and the Group’s exposure to bad debts is not significant.

The credit risk of the Group’s other financial assets, which comprise cash and bank balances, trade receivables, financial assets included in prepayments, deposits and other receivables and other non-current assets, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

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39. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification. The amounts presented are gross carrying amounts for financial assets.

As at December 31, 2024

	12-month ECLs	Lifetime ECLs			
	Stage 1 RMB	Stage 2 RMB	Stage 3 RMB	Simplified approach RMB	Total RMB
Financial assets included in prepayments, other receivables and other assets - Normal**	9,846	-	-	-	9,846
Cash and bank balances - Not yet past due	1,261,211	-	-	-	1,261,211
Trade receivables*	-	-	-	83,143	83,143
Financial assets included in other non-current assets - Normal**	2,439	-	-	-	2,439
Total	1,273,496	-	-	83,143	1,356,639

As at December 31, 2025

	12-month ECLs	Lifetime ECLs				
	Stage 1 RMB	Stage 2 RMB	Stage 3 RMB	Simplified approach RMB	Total RMB	Total US\$
Financial assets included in prepayments, other receivables and other assets - Normal**	3,609	-	-	-	3,609	516
Cash and bank balances - Not yet past due	2,470,085	-	-	-	2,470,085	353,217
Trade receivables*	-	-	-	252,938	252,938	36,170
Financial assets included in other non-current assets - Normal**	690	-	-	-	690	99
Total	2,474,384	-	-	252,938	2,727,322	390,002

* For trade receivables to which the Group applies the simplified approach for impairment, information based on provision matrix is disclosed in note 21 to the financial statements.

** The credit quality of the financial assets included in prepayments, other receivables and other assets and financial assets included in other non-current assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

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39. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

Liquidity risk

The Group’s objective is to maintain a balance between continuity of funding and flexibility through the use of bank loans, lease liabilities and other interest-bearing loans. As at December 31, 2025, 62% (2024: 47%) of the Group’s borrowings would mature in less than one year based on the carrying values of the borrowings.

The maturity profile of the Group’s financial liabilities as at the end of the reporting period, based on the contractual undiscounted payments, is as follows:

As at December 31, 2024

	On demand RMB	Less than 1 year RMB	1 to 5 years RMB	Over 5 years RMB	Total RMB
Trade payables	-	91,966	-	-	91,966
Lease liabilities	-	10,674	8,592	-	19,266
Interest-bearing bank and other borrowings (excluding lease liabilities)	-	813,610	452,765	565,079	1,831,454
Financial liabilities included in other payables and accruals	73,670	29,344	-	-	103,014
Other non-current liabilities	-	-	6,274	-	6,274
Total	73,670	945,594	467,631	565,079	2,051,974

As at December 31, 2025

	On demand RMB	Less than 1 year RMB	1 to 5 years RMB	Over 5 years RMB	Total RMB	Total US\$
Trade payables	-	106,740	-	-	106,740	15,264
Lease liabilities	-	8,262	16,226	-	24,488	3,502
Interest-bearing bank and other borrowings (excluding lease liabilities)	-	1,255,814	365,732	546,806	2,168,352	310,070
Financial liabilities included in other payables and accruals	130,142	10,308	-	-	140,450	20,084
Other non-current liabilities	-	-	12,031	-	12,031	1,720
Total	130,142	1,381,124	393,989	546,806	2,452,061	350,640

Equity price risk

Equity price risk is the risk that the fair values of equity securities decrease as a result of changes in the levels of equity indices and the value of individual securities. The Group is exposed to equity price risk arising from individual equity investments included in financial assets at FVTPL (note 17) as at December 31, 2025. The Group’s listed investments held in the prior year were listed on NASDAQ and were valued at the quoted market price at the end of the reporting period, whereas the investments in the current year don’t involve publicly traded market quotations.

The market equity index for the following stock exchange, at the close of business of the nearest trading day in the year to the end of the reporting period, and its respective highest and lowest points during the year were as follows:

	December 31, 2024	High/low 2024	December 31, 2025	High/low 2025
United States–NASDAQ index	19,311	20,205/14,478	-	-/-

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39. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

Equity price risk (continued)

The following table demonstrates the sensitivity to every 5% change in the fair values of the equity investments, with all other variables held constant and before any impact on tax, based on their carrying amounts at the end of the reporting period.

	Carrying amount of equity investments	Decrease/ (increase) in loss before tax
	RMB	RMB
2024		
Investments listed in:		
NASDAQ - Financial assets at fair value through profit or loss	1,141	57
		(57)
2025		
Investments listed in:		
NASDAQ - Financial assets at fair value through profit or loss	-	-
NASDAQ - Financial assets at fair value through profit or loss in USD	-	-

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. No changes were made in the objectives, policies or processes for managing capital during the reporting year.

The Group monitors capital using a gearing ratio, which is net debt divided by the adjusted capital plus net debt. Net debt includes interest-bearing bank and other borrowings, trade payables, financial liabilities included in other payables and accruals and long-term payables, less cash and bank balances. Capital includes equity attributable to owners of the parent. The gearing ratios as at the end of the reporting periods were as follows:

	As at December 31,		
	2024	2025	2025
	RMB	RMB	US\$
Interest-bearing bank and other borrowings	1,668,497	1,979,719	283,096
Trade payables	91,966	106,740	15,264
Financial liabilities included in other payables and accruals	103,014	140,450	20,084
Other non-current liabilities	6,274	12,031	1,720
Less: Cash and bank balances	(1,261,211)	(2,470,085)	(353,217)
Net debt	608,540	(231,145)	(33,053)
Equity attributable to owners of the parent	264,194	1,324,462	189,396
Adjusted capital	264,194	1,324,462	189,396
Capital and net debt	872,734	1,093,317	156,343
Gearing ratio	70%	NA	NA

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40. EVENT AFTER THE REPORTING PERIOD

As at the date of approval of these financial statements, there have been no significant events after the end of the reporting period.

41. CONDENSED FINANCIAL INFORMATION OF THE COMPANY

Statements of financial position of the Company

	As at December 31,		
	2024 RMB	2025 RMB	2025 US\$
NON-CURRENT ASSETS			
Investments in subsidiaries	380,339	448,431	64,125
Other non-current Asset	30,529	29,851	4,269
Total non-current assets	410,868	478,282	68,394
CURRENT ASSETS			
Prepayments, other receivables and other assets	3,986,172	4,806,759	687,358
Cash and bank balances	470,170	1,841,572	263,341
Total current assets	4,456,342	6,648,331	950,699
CURRENT LIABILITIES			
Other payables and accruals	24,187	2,382	341
Total current liabilities	24,187	2,382	341
NET CURRENT ASSETS	4,432,155	6,645,949	950,358
TOTAL ASSETS LESS CURRENT LIABILITIES	4,843,023	7,124,231	1,018,752
Net assets	4,843,023	7,124,231	1,018,752
EQUITY			
Share capital	214	256	37
Treasury shares	(8)	(2,961)	(423)
Capital and reserves	5,652,916	8,011,879	1,145,683
Exchange fluctuation reserve	108,598	(40,959)	(5,857)
Accumulated losses	(918,697)	(843,984)	(120,688)
Total equity	4,843,023	7,124,231	1,018,752

Condensed statements of comprehensive income

	2023 RMB	2024 RMB	2025 RMB	2025 US\$
Other income and gains	18,597	17,925	102,560	14,666
Operating expenses	(8,118)	(9,983)	(27,800)	(3,975)
Other expenses	(24,741)	(21,585)	(47)	(7)
LOSS BEFORE TAX	(14,262)	(13,643)	74,713	10,684
LOSS FOR THE YEAR	(14,262)	(13,643)	74,713	10,684
Exchange differences on translation	84,629	67,715	(149,557)	(21,386)
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	70,367	54,072	(74,844)	(10,702)

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41. CONDENSED FINANCIAL INFORMATION OF THE COMPANY (continued)

Condensed statements of cash flows

	For the years ended December 31,			
	2023	2024	2025	2025
	RMB	RMB	RMB	US\$
Net cash generated from(used in) operating activities	9,727	(41,686)	123,427	17,650
Net cash used in investing activities	(535,395)	(589,153)	(1,850,400)	(264,604)
Net cash generated from financing activities	464,166	531,922	2,229,331	318,790
Effect of foreign exchange rate changes, net	1,581	9,311	(56,093)	(8,021)
Net (decrease)/increase in cash and cash equivalents	(59,921)	(89,606)	446,265	63,815

A summary of the Company’s reserves is as follows:

	Capital and reserves	Exchange Fluctuation reserve	Accumulated losses	Total
	RMB	RMB	RMB	RMB
At January 1, 2023	4,526,096	(43,746)	(890,792)	3,591,558
Loss for the year	-	-	(14,262)	(14,262)
Other comprehensive income for the year:				
Exchange differences on translation of the Company	-	84,629	-	84,629
Total comprehensive income for the year	-	84,629	(14,262)	70,367
Issue of ordinary shares	470,066	-	-	470,066
Employees share-based compensation scheme				
Pre-IPO share option expenses	3,750	-	-	3,750
RSU expenses	27,753	-	-	27,753
Exercise of Pre-IPO share options	7	-	-	7
Vesting of RSUs	(11,123)	-	-	(11,123)
Equity-settled bonus	55,466	-	-	55,466
At December 31, 2023 and January 1, 2024	5,072,015	40,883	(905,054)	4,207,844
Loss for the year	-	-	(13,643)	(13,643)
Other comprehensive income for the year:				
Exchange differences on translation of the Company	-	67,715	-	67,715
Total comprehensive income for the year	-	67,715	(13,643)	54,072
Issue of ordinary shares	533,923	-	-	533,923
Employees share-based compensation scheme				
RSU expenses	20,924	-	-	20,924
Exercise of Pre-IPO share options	6	-	-	6
Vesting of RSUs	(14,671)	-	-	(14,671)
Equity-settled bonus	40,719	-	-	40,719
At December 31, 2024 and January 1, 2025	5,652,916	108,598	(918,697)	4,842,817
Loss for the year	-	-	74,713	74,713
Other comprehensive income for the year:				
Exchange differences on translation of the Company	-	(149,557)	-	(149,557)
Total comprehensive income for the year	-	(149,557)	74,713	(74,844)
Issue of ordinary shares	2,279,855	-	-	2,279,855
Employees share-based compensation scheme				
Post-IPO share option expenses	2,420	-	-	2,420
RSU expenses	18,454	-	-	18,454
Exercise of Pre-IPO share options	4	-	-	4
Vesting of RSUs	(638)	-	-	(638)
Equity-settled bonus	58,868	-	-	58,868
At December 31, 2025	8,011,879	(40,959)	(843,984)	7,126,936
At December 31, 2025 in US\$	1,145,683	(5,857)	(120,688)	1,019,138

ASCENTAGE PHARMA GROUP INTERNATIONAL

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands of Renminbi (“RMB”) and US dollars (“US\$”)
except for number of shares and per share data)

41. CONDENSED FINANCIAL INFORMATION OF THE COMPANY (continued)

a) Basis of presentation

The separate condensed financial statements above have been presented on a “parent company only” basis. Under a “parent company only” presentation, the Company’s investment in its subsidiaries is presented at cost. Such investment is presented on the separate condensed statements of financial position of the Company as “Investment in subsidiaries”.

The subsidiaries did not pay any dividends to the Company for the periods presented.

There were no indicators of impairment associated with the investment in subsidiaries as of December 31, 2024 and 2025.

Certain information and note disclosures normally included in financial statements prepared in accordance with IFRS Accounting Standards have been condensed or omitted in this parent company only condensed financial information by reference to the Group’s consolidated financial statements.

b) Commitments

The Company does not have any significant commitments or long-term obligations as of December 31, 2024 and 2025.

42. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorized for issue by the board of directors on April 29, 2026.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

The following description sets forth certain material terms of the ordinary shares of Ascentage Pharma Group International ("Ascentage Pharma," the "Company," "we," "us," and "our") that are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our second amended and restated memorandum and articles of association (the "A&R Articles") and the Companies Act (as amended) of the Cayman Islands (the "Companies Act") insofar as they relate to the material terms of our ordinary shares. The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of the laws of the Cayman Islands and our A&R Articles, a copy of which is filed as an exhibit to the Annual Report on 20-F of which this exhibit is a part.

General

We are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our A&R Articles, the Companies Act, and Cayman Islands common law.

Our securities include our ordinary shares, par value US\$0.0001 per share, in the form of American Depositary Shares (the "ADSs"), each representing four ordinary shares, no par value per share.

The ADSs are listed on the Nasdaq Global Market ("Nasdaq") under the trading symbol "AAPG."

Our ordinary shares are listed on the Hong Kong Stock Exchange ("HKEx") under the stock code "6855."

The following is a description of the rights of (i) the holders of ordinary shares and (ii) ADS holders. The ordinary shares underlying the ADSs are held by JPMorgan Chase Bank, N.A. ("JPMorgan"), as depositary, and holders of ADSs will not be treated as holders of the ordinary shares.

Description of ordinary shares

General

Our authorized share capital is US\$50,000 consisting of 500,000,000 shares, par value US\$0.0001 per share. As of April 1, 2026, 373,322,192 ordinary shares were issued and outstanding. Certificates representing the ordinary shares are issued in registered form. We may not issue share to bearer. Our shareholders who are non-residents of the Cayman Islands may freely hold and transfer their ordinary shares.

Dividends

The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors subject to our A&R Articles and the Companies Act. In addition, our shareholders may, subject to the provisions of our A&R Articles, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Our A&R Articles provide that dividends may be declared and paid out of our profits, realized or unrealized, or from any reserve set aside from profits which our board of directors determine is no longer needed. Dividends may also be declared and paid out of share premium account or any other fund or account which can be authorized for this purpose in accordance with the Companies Act. No dividend may be declared and paid unless our directors determine that, immediately after the payment, we will be able to pay our debts as they become due in the ordinary course of business and we have funds lawfully available for such purpose.

Voting rights

In respect of all matters subject to a shareholders' vote, each ordinary share is entitled to one vote for each ordinary share registered in his or her name on our register of members. Voting at any meeting of shareholders is by poll, except that the chairman of the meeting may, pursuant to Hong Kong Listing Rules, allow a resolution to be voted by a show of hands.

A quorum required for a meeting of shareholders consists of two shareholders entitled to vote at general meetings present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our A&R Articles provide that in each financial year, we will hold a general meeting as our annual general meeting in addition to any other meeting in that year and will specify the meeting as such in the notice calling it. We will hold the annual general meeting within six months after the end of our financial year. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Shareholders' annual general meetings and any other general meetings of our shareholders may be called by a majority of our board of directors or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than one-third of the votes attaching to the issued and outstanding shares entitled to vote at general meetings, in which case the directors are obliged to call such meeting and to put the resolutions so requisitioned to a vote at such meeting; however, our A&R Articles do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders. Advance notice of at least 21 days is required for the convening of our annual general meeting and other general meetings shall be called by at least 14 days' notice in writing in accordance with our A&R Articles.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast by those shareholders entitled to vote who are present in person or by proxy at a general meeting, while a special resolution also requires the affirmative vote of no less than three quarters of the votes attaching to the ordinary shares cast by those shareholders entitled to vote who are present in person or by proxy at a general meeting. A special resolution will be required for important matters such as a change of name or making changes to our A&R Articles.

Transfer of ordinary shares

Subject to the restrictions in our A&R Articles, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;

- the instrument of transfer is in respect of only one class of shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four;
- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Hong Kong Stock Exchange may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, *provided, however*, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year as our board may determine.

Liquidation

On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares or, on a winding up, with the sanction of a special resolution of our company and any other sanction required by the Companies Act and subject to any special rights, privileges or restrictions as to the distribution of available surplus assets on liquidation attached to any class or classes of shares), assets available for distribution among the holders of ordinary shares will be distributed among the holders of the ordinary shares in proportion to the paid up par value of the shares held by them. If our assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the paid up par value of the shares held by them. We are an exempted “limited liability” company registered under the Companies Act, and under the Companies Act, the liability of our members is limited to the amount, if any, unpaid on the shares respectively held by them. Our current A&R Articles contain a declaration that the liability of our members is so limited.

If our Company is wound up (in whatever manner), the liquidator may, with the sanction of a special resolution and any other sanction required by the Companies Act, divide among our shareholders in specie or kind the whole or any part of the assets of our Company whether the assets shall consist of property of one kind or shall consist of properties of different kinds and the liquidator may, for such purpose, set such value as it deems fair upon any one or more class or classes of property to be divided and may determine how such division shall be carried out as amongst our shareholders. The liquidator may, with the like sanction, vest any part of the assets in trustees upon such trusts for the benefit of our shareholders as the liquidator, with the like sanction, shall think fit, but so that no shareholder shall be compelled to accept any of our ordinary shares or other assets upon which there is a liability.

Calls on ordinary shares and forfeiture of ordinary shares

Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their ordinary shares in a notice served to such shareholders at least 14 clear days prior to the specified time of payment. The ordinary shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, repurchase and surrender of ordinary shares

We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders thereof, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by an ordinary resolution of our shareholders. Our company may also repurchase any of our ordinary shares provided that the manner and terms of such purchase have been approved by our board of directors or by ordinary resolution of our shareholders or are otherwise authorized by our A&R Articles. Under the Companies Act, the redemption or repurchase of any share may be paid out of our company's profits or out of the proceeds of a fresh issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if the company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding, or (c) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variations of rights of shares

If at any time our share capital is divided into different classes or series of shares, the rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our company is being wound- up, may be varied with the consent in writing of three fourths of the voting rights of the holders of that class or series or with the sanction of a special resolution at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Anti-Takeover Provisions

Some provisions of our A&R Articles may discourage, delay or prevent a change in control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our A&R Articles, as amended and restated from time to time, for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Rights of Non-resident or Foreign Shareholders

There are no limitations imposed by our A&R Articles on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our ordinary shares. In addition, there are no provisions in our A&R Articles governing the ownership threshold above which shareholder ownership must be disclosed.

Inspection of books and records

Holders of our ordinary shares have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records (other than our A&R Articles, the register of mortgages and charges and any special resolutions passed by shareholders). However, under our A&R Articles, during the period when our shares are listed on the Hong Kong Stock Exchange and except when our register of shareholders is closed on terms equivalent to Section 632 of the Hong Kong Companies Ordinance, any of our shareholders may inspect during business hours any register of shareholders maintained in Hong Kong without charge and require the copies of extracts of it. Under Cayman Islands law, the names of our current directors can be obtained from a search conducted at the Registrar of Companies of the Cayman Islands. The books of account shall be kept at our headquarters or at such other place or places as our board of directors thinks fit and shall always be open to the inspection of the members of our board of directors. No shareholder (unless otherwise a member of our board of directors) or other person shall have any right of inspecting any account or book or document of our Company except as conferred by the Companies Act or ordered by a court of competent jurisdiction or authorized by our board of directors or our Company at a general meeting of shareholders.

Issuance of additional shares

Our A&R Articles authorize our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our A&R Articles also authorize our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Exempted company

We are an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue shares with no par value;
- may obtain an undertaking against the imposition of any future taxation;
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on that shareholder’s shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Register of members

Under the Companies Act, we must keep a register of members and there should be entered therein:

- the names and addresses of our members, a statement of the shares held by each member, and of the amount paid or agreed to be considered as paid, on the shares of each member;
- the date on which the name of any person was entered on the register as a member; and
- the date on which any person ceased to be a member.

Under the Companies Act, the register of members of our company is prima facie evidence of the matters set out therein (that is, the register of members will raise a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members is deemed as a matter of the Companies Act to have legal title to the shares as set against its name in the register of members. The shareholders recorded in the register of members will be deemed to have legal title to the shares set against their name.

If the name of any person is incorrectly entered in or omitted from our register of members, or if there is any default or unnecessary delay in entering on the register the fact of any person having ceased to be a member of our company, the person or member aggrieved (or any member of our company or our company itself) may apply to the Grand Court of the Cayman Islands for an order that the register be rectified, and the Court may either refuse such application or it may, if satisfied of the justice of the case, make an order for the rectification of the register.

Differences in corporate law

The Companies Act differs from laws applicable to corporations incorporated in the State of Delaware and their stockholders. Set forth below is a summary of the significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the State of Delaware and their stockholders.

	Cayman Islands	Delaware
Title of Organizational Documents	Memorandum and Articles of Association	Certificate of Incorporation and Bylaws
Duties of Directors	As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company-a duty to act in good faith in the best interests of the company, a duty not to make a personal profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.	Under Delaware law, the business and affairs of a corporation are managed by or under the direction of its board of directors. In exercising their powers, directors are charged with a fiduciary duty of care to protect the interests of the corporation and a fiduciary duty of loyalty to act in the best interests of the company and its stockholders. The duty of care requires that directors act in an informed and deliberative manner and inform themselves, prior to making a business decision, of all material information reasonably available to them. The duty of care also requires that directors exercise care in overseeing and investigating the conduct of the corporation’s employees. The duty of loyalty may be summarized as the duty to act in good faith, not out of self-interest, and in a manner which the director reasonably believes to be in the best interests of the stockholders.

Limitations on Personal Liability of Directors and Officers

The Companies Act has no equivalent provision to Delaware law regarding the limitation of director's liability. However, any provision which seeks to limit the liability of directors or officers to the extent that the liability is a consequence of the director or officer's own fraud, dishonesty or willful default is unlikely to be enforceable as a matter of common law.

Subject to the limitations described below, a certificate of incorporation may provide for the elimination or limitation of the personal liability of a director to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director. Such provision cannot limit liability for breach of the fiduciary duty of loyalty, acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, a transaction from which the director derived an improper personal benefit, unlawful payment of dividends or unlawful stock repurchase or redemption. Similarly, a certificate of incorporation may provide for the elimination or limitation of the personal liability of specified officers to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as an officer. Such provision cannot limit liability for breach of loyalty, acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, a transaction from which the officer derived an improper personal benefit, or with respect to actions by or in the right of the corporation. In addition, an exculpatory provision with terms described above cannot limit liability for any act or omission occurring prior to the date when such provision becomes effective.

Indemnification of Directors, Officers, Agents and Others

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of directors and officers, except to the extent any such provision may be held by the Cayman Islands Court to be contrary to public policy, such as to provide indemnification against the consequences of committing a crime, or against the indemnified person's own fraud, dishonesty or willful default.

Our A&R Articles provide that we will indemnify each director, managing director, alternate director, auditor, secretary and other officer of the company and the trustees (if any) for the time being acting in relation to any of our affairs, and their respective executors or administrators against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such person by reason of any act done, concurred in or omitted in or about the execution of their duty or supposed duty in their respective offices or trusts, other than by reason of such person's own dishonesty or fraud. In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our A&R Articles.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

A corporation has the power to indemnify any director, officer, employee, or agent of the corporation who was, is or is threatened to be made a party to an action, suit or proceeding who acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and if with respect to a criminal proceeding (other than an action by or in the right of the corporation), had no reasonable cause to believe his or her conduct would be unlawful, against amounts actually and reasonably incurred. A corporation also has the power to indemnify any director, officer, employee, or agent of the corporation who was, is or is threatened to be made a party to an action or suit by or in the right of the corporation to procure a judgment in the corporation's favor against expenses (including legal fees) actually and reasonably incurred if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and only if the person is not found liable, unless a court determines the person is fairly and reasonably entitled to the indemnification. Additionally, under the Delaware General Corporation Law, a Delaware corporation must indemnify its present or former directors and officers against expenses (including attorneys' fees) actually and reasonably incurred to the extent that the officer or director has been successful on the merits or otherwise in defense of any action, suit or proceeding brought against him or her by reason of the fact that he or she is or was a director or officer of the corporation.

Interested Directors

Under our A&R Articles, directors who are in any way, whether directly or indirectly, interested in a contract or proposed contract with our company must declare the nature of their interest at a meeting of the board of directors. Following such declaration, a director may vote in respect of any certain contract or proposed contract notwithstanding his or her interest, provided that in exercising any such vote, such director's duties remain as described above.

Under Delaware law, a transaction in which a director has an interest is not void or voidable solely because of such interest or solely because such interested director is present at or participates in the meeting that authorizes the transaction if: (1) the material facts as to such interested director's relationship or interests and as to the transaction are disclosed or are known to the board of directors or committee thereof and the board or committee in good faith authorizes the transaction by the affirmative vote of a majority of the disinterested directors, even though the disinterested directors are less than a quorum; (2) such material facts are disclosed or are known to the stockholders entitled to vote on such transaction and the transaction is specifically approved in good faith by vote of the stockholders; or (3) the transaction is fair as to the corporation as of the time it is authorized, approved or ratified by the board of directors, a committee of the board, or the stockholders. Under Delaware law, a director or officer could be held liable for any transaction in which such director or officer derived an improper personal benefit.

Voting Requirements

As a matter of Cayman Islands law, certain matters must be approved by special resolution of the shareholders, including amending or adopting memorandum or articles of association of a Cayman Islands company, reduction of share capital, change of name, authorization of a plan of merger, voluntary winding up of the company or the recalling of the voluntary liquidation of the company.

The Companies Act requires that a special resolution be passed by a majority of at least two-thirds or such higher percentage as set forth in the articles of association, of shareholders being entitled to vote and do vote in person or by proxy at a general meeting, or by unanimous written consent of shareholders entitled to vote at a general meeting.

The Companies Act defines “special resolutions” only. A company’s articles of association can therefore tailor the definition of “ordinary resolutions” as a whole, or with respect to specific provisions. Our A&R Articles provide that an ordinary resolution is a resolution (1) passed by a simple majority of such shareholders as, being entitled to do so, vote in person (or, where proxies are allowed, by proxy) at a general meeting and regard shall be had in computing a majority to the number of votes to which each shareholder is entitled or (2) approved in writing by all of the shareholders entitled to vote at a general meeting in one or more instruments each signed by one or more of the shareholders and the effective date of the resolution so adopted shall be the date on which the instrument (or the last of such instruments, if more than one) is executed.

Under Delaware law, each stockholder is entitled to one vote for each share of capital stock held by such stockholder as of the applicable record date, unless otherwise provided in a corporation’s certificate of incorporation. Except as otherwise provided under the Delaware General Corporation Law or by the corporation’s certificate of incorporation or bylaws, under Delaware law, all matters brought before a meeting of stockholders at which a quorum is present (other than the election of directors) require the affirmative vote of the majority of the shares present in person or represented by proxy and entitled to vote on the subject matter. Certain matters for stockholder approval, including the approval of certain merger agreements, the statutory conversion or domestication of the corporation, certain amendments to the certificate of incorporation, and the sale, lease, or exchange of all or substantially all of the corporation’s assets will require approval of the holders of a majority of the outstanding capital stock. The certificate of incorporation may also include a provision requiring supermajority approval by the directors or stockholders for any corporate action.

In addition, under Delaware law, certain business combinations involving certain interested stockholders of publicly traded corporations may require approval by a supermajority of the non-interested stockholders.

Voting for Directors

Our A&R Articles provide that our directors may be appointed by a resolution of our board of directors to fill a casual vacancy on the board of directors or as an addition to the board of directors or by an ordinary resolution of our shareholders.

Under Delaware law, unless otherwise specified in the certificate of incorporation or bylaws of the corporation, directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

Cumulative Voting

There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands.

There is no cumulative voting for the election of directors unless provided for in the certificate of incorporation.

Our A&R Articles do not provide for cumulative voting on the election of the directors as described above.

Directors' Powers Regarding Bylaws

Our A&R Articles may only be amended by a special resolution of the shareholders of our company.

The certificate of incorporation may grant the directors the power to adopt, amend or repeal bylaws.

***Nomination and Removal of Directors and Filling
Vacancies on Board***

Nomination and removal of directors and filling of board vacancies are governed by the terms of the articles of association. Our A&R Articles provide that our shareholders may by ordinary resolution remove any of our director (including a managing director or other executive director) before the expiration of his or her term of office notwithstanding anything in our A&R Articles or in any agreement between our Company and such director (but without prejudice to any claim which such director may have for damages for any breach of any contract between him/her and our Company) and may by ordinary resolution elect another person in his or her stead. At each annual general meeting one-third of our directors for the time being, or, if their number is not three or a multiple of three, then the number nearest to but not less than one-third, shall retire from office by rotation provided that every director (including those appointed for a specific term) shall be subject to retirement by rotation at least once every three years. A retiring Director shall be eligible for re-election.

In addition, a director's office shall be vacated if the director (1) becomes bankrupt or makes any arrangement or composition with his creditors; (2) dies or is found to be or becomes of unsound mind; (3) is absent from our board meetings during a continuous period of six (6) months, without special leave of our board, and his or her alternate director (if any) has not attended in his or her stead during the period; (4) is prohibited by law from acting as a director; (5) has been validly required by the relevant stock exchange to cease to be a director; (6) resigns his office by notice in writing to the company; or (7) is removed from office pursuant to any other provisions of our A&R Articles.

Stockholders may generally nominate directors if they comply with any applicable advance notice provisions and other procedural requirements in the corporation's bylaws.

Holders of a majority of the shares then entitled to vote at an election of directors may remove a director with or without cause, except in certain cases involving a classified board or if the company uses cumulative voting. Unless otherwise provided for in the certificate of incorporation or bylaws, directorship vacancies and newly created directorships may be filled by a majority of the directors elected or then in office, or by the stockholders.

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (1) “merger” means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (2) a “consolidation” means the combination of two or more constituent companies into a combined company and the vesting of the undertaking, property and liabilities of such companies to the combined company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (1) a special resolution of the shareholders of each constituent company, and (2) such other authorization, if any, as may be specified in such constituent company’s articles of association. The plan must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures. Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions.

In addition, there are statutory provisions that facilitate, compromises or arrangements between a Cayman Islands company and its members (or any class of them).

Under Delaware law, with certain exceptions, a merger, a consolidation, a statutory conversion or domestication of the corporation, or a sale, lease or exchange of all or substantially all the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. However, unless required by its certificate of incorporation, approval is not required by the holders of the outstanding stock of a constituent corporation surviving a merger if:

- the merger agreement does not amend in any respect its certificate of incorporation;
- each share of its stock outstanding prior to the merger will be an identical share of stock following the merger; and
- either no shares of the surviving corporation’s common stock and no shares, securities or obligations convertible into such stock will be issued or delivered pursuant to the merger, or the authorized unissued shares or treasury shares of the surviving corporation’s common stock to be issued or delivered pursuant to the merger plus those initially issuable upon conversion of any other shares, securities or obligations to be issued or delivered pursuant to the merger do not exceed 20% of the shares of the surviving corporation’s common stock outstanding immediately prior to the effective date of the merger.

A merger between a parent entity and its Delaware subsidiary does not require authorization by a resolution of the board of directors or stockholders of that subsidiary if the board of directors of the parent corporation approves the terms of such merger and a certificate of ownership and merger is filed. For this purpose a company is a “parent” of a subsidiary if it holds at least 90% of the outstanding shares of each class of the stock of the subsidiary that has voting power.

Following amendments to the Companies Act that became effective on August 31, 2022, the majority-in-number “headcount test” in relation to the approval of members’ schemes of arrangement has been abolished.

Section 86(2A) of the Companies Act provides that, if 75% in value of the members (or class of members) of a Cayman Islands company agree to any compromise or arrangement, such compromise or arrangement shall, if sanctioned by the Cayman Court, be binding on all members (or class of members) of such company and on the company itself. Where a Cayman Islands company is in the course of being wound up, such compromise or arrangement would be binding on the liquidator and contributories of the company. In contrast, section 86(2) of the Companies Act continues to require (a) approval by a majority in number representing 75% in value; and (b) the sanction of the Grand Court of the Cayman Islands, in relation to any compromise or arrangement between a company and its creditors (or any class of them). At the initial directions hearing, the Cayman Islands court will make orders for (amongst other things) the convening of the meetings of creditors or members (or classes of them, as applicable). While a dissenting shareholder or creditor has the right to express to the court the view that the transaction ought not to be approved, the court would nevertheless be likely to approve the arrangement if it determines that:

- the company has complied with the directions set down by the Cayman Islands court;

Under the Delaware General Corporation Law, a stockholder of record or beneficial owner of capital stock of a Delaware corporation generally has the right to dissent from and request payment of the fair value (excluding value arising from the accomplishment or expectation of the transaction) for such person’s shares upon a merger, consolidation, statutory conversion or domestication in which the Delaware corporation is participating, subject to specified procedural requirements, including that such person does not vote in favor of the transaction. However, the Delaware General Corporation Law does not confer appraisal rights in certain circumstances, including if the dissenting stockholder or beneficial owner owns shares traded on a national securities exchange and will receive publicly traded shares in the transaction. Under the Delaware General Corporation Law, a person asserting appraisal rights does not receive any payment for their shares until a court determines the fair value of the shares. The costs of the proceeding may be determined by the court and assessed against the parties as the court deems equitable under the circumstances.

- the meeting was properly held and the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class; and
- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his/her interest.

If a compromise or arrangement of a Cayman Islands company is approved by the members in the context of a members' scheme and the Cayman Islands court subsequently sanctions such scheme (as described above), a dissenting shareholder would have no rights comparable to the appraisal rights which it would have if the company in question were a Delaware corporation (being the right to receive payment in cash for the judicially determined value of its shares). This is because such scheme will be binding on all members (or class of members), regardless of whether all the members (or class of members) approved the scheme, upon the sanction order being made. Having said that, a dissenting shareholder would have the right to appeal the making of the sanction order to the Cayman Islands Court of Appeal, if there were grounds for doing so.

In principle, we will normally be the proper plaintiff to sue for a wrong done to us as a company, and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands court can be expected to follow and apply the common law principles so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a “fraud on the minority.”

A shareholder may also (subject to meeting the relevant requirements in the Companies Act) file winding up proceedings against our company on just and equitable grounds, based on similar factual circumstances. It is possible for the shareholder to seek alternative remedies to a winding up within the winding up petition, depending on the circumstances. Such alternative remedies include seeking a share buyout order from our company or seeking an order regulating the conduct of our company’s affairs in the future.

Class actions and derivative actions generally are available to stockholders who satisfy certain procedural requirements under Delaware law for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court generally has discretion to permit a winning plaintiff to recover attorneys’ fees incurred in connection with such action.

Inspection of Corporate Records

Shareholders of a Cayman Islands exempted company have no general right under Cayman Islands law to inspect or obtain copies of the register of members or other corporate records (other than the memorandum and articles of association and the register of mortgages and charges) of the company. However, these rights may be provided in the company's articles of association.

Under Delaware law, stockholders of a Delaware corporation have the right during normal business hours to inspect for any proper purpose, and to obtain copies of lists of stockholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation. A complete list of the stockholders entitled to vote at a stockholders' meeting generally must be available for stockholder inspection for a purpose germane to the meeting at least ten days before the meeting.

Shareholder Proposals and Calling of Special Shareholder Meetings

The Companies Act provide shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our A&R Articles allow our shareholders holding in aggregate not less than one tenth or more of the paid up capital of the Company having the right of voting at general meetings, on a one vote per share basis, in the share capital of the Company, permitted to be exercised at any such meeting to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. Other than this right to requisition a shareholders' meeting, our A&R Articles do not provide our shareholders with any other right to put proposals before annual general meetings or extraordinary general meetings. As an exempted Cayman Islands company, we are not obliged by law to call shareholders' annual general meetings, but our A&R Articles provide that we will do so for so long as our ordinary shares are traded on the HKEx.

Unless provided in the corporation's certificate of incorporation or bylaws, Delaware law does not include a provision restricting the manner in which stockholders may bring business before a meeting.

Delaware law permits the board of directors or any person who is authorized under a corporation's certificate of incorporation or bylaws to call a special meeting of stockholders.

Approval of Corporate Matters by Written Consent

The Companies Act provide that shareholders may approve corporate matters by way of unanimous written resolutions signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held (if authorized by the articles of association).

Delaware law provides that, unless otherwise provided in the certificate of incorporation, stockholders may take action by written consent signed by the holders of outstanding shares having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting of stockholders at which all shares entitled to vote thereon were present and voted.

Dissolution; Winding Up

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. Further, the Grand Court of the Cayman Islands has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the Court, just and equitable to do so.

Under Delaware law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by stockholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated and approved by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board. A Delaware corporation may also be dissolved by decree or judgment of a Delaware court in certain circumstances.

Variation of Rights of Shares

Under Cayman Islands law and our A&R Articles, whenever our share capital is divided into more than one class of shares (and as otherwise determined by the directors), subject to any rights or restrictions for the time being attached to any shares, we may materially adversely vary the rights attached to any class with the written consent of the holders of not less than three-fourths of the voting rights of the holders of such class or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of that class by a majority of two-thirds of the votes cast at such meeting. The necessary quorum (other than at an adjourned meeting) of such meeting shall be not less than persons holding (or, in the case of a shareholder being a corporation, by its duly authorized representative) or representing by proxy holding one-third of the issued shares of such class, that the quorum for any meeting adjourned for want of quorum shall be two shareholders present in person (or in the case of the shareholder being a corporation, by its duly authorized representative) or by proxy (whatever the number of shares held by them) and that any holder of shares of the class present in person (or in the case of the shareholder being a corporation, by its duly authorized representative) or by proxy may demand a poll.

Under Delaware law, a corporation may vary the rights of a class of shares with the approval of both a majority of the outstanding shares of capital stock of the corporation and a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Delaware law, a corporation may also vary the rights of a series of a class of shares, but not the entire class, with the approval of both a majority of the outstanding shares of capital stock of the corporation and a majority of the outstanding shares of such series, unless the certificate of incorporation provides otherwise.

Dividends and Stock Repurchases

Subject to any rights and restrictions for the time being attached to any shares, or as otherwise provided for in the Companies Act and our A&R Articles, our directors may from time to time declare dividends (including interim dividends) and other distributions on shares in issue and authorize payment of the same.

Subject to any rights and restrictions for the time being attached to any shares, our Company by ordinary resolution may declare dividends, but no dividend shall exceed the amount recommended by our directors.

The Delaware General Corporation Law provides that, subject to any restrictions in a corporation's certificate of incorporation, dividends may be declared from the corporation's surplus, or, if there is no surplus, from its net profits for the fiscal year in which the dividend is declared and for the preceding fiscal year, and Delaware common law also imposes a solvency requirement with respect to the payment of dividends. Dividends may not be declared out of net profits, however, if the corporation's capital has been diminished to an amount less than the aggregate amount of all capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets until the deficiency in the amount of capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets is repaired. Furthermore, applicable Delaware statutory and common law generally provides that a corporation may redeem or repurchase its shares only if the redemption or repurchase would not impair the capital of the corporation and only if the corporation is solvent at the time of the redemption or repurchase, and the redemption or repurchase would not render the corporation insolvent.

Anti-Takeover Provisions

Some provisions of our A&R Articles may discourage, delay or prevent a change in control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our A&R Articles, as amended and restated from time to time, for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Unless a corporation opts out of the provisions of Section 203 of the Delaware General Corporation Law, Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with a holder of 15% or more of the corporation's voting stock (as defined in Section 203), referred to as an interested stockholder, for a period of three years after the date of the transaction in which the interested stockholder became an interested stockholder, except as otherwise provided in Section 203. For these purposes, the term "business combination" includes mergers, assets sales and other similar transactions with an interested stockholder.

Rights of Non-resident or Foreign Shareholders

There are no limitations imposed by our A&R Articles on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our ordinary shares. In addition, there are no provisions in our A&R Articles governing the ownership threshold above which shareholder ownership must be disclosed.

There are no limitations in the Delaware General Corporation Law related to rights of non-resident or foreign stockholders to hold or exercise voting rights of a Delaware corporation.

Description of American depositary shares

American depositary receipts

JPMorgan, as depositary, is the issuer of the ADSs. Each ADS represents an ownership interest in a designated number or percentage of ordinary shares that we have deposited with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary, and all holders and beneficial owners from time to time of American depositary receipts issued thereunder.

The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

The ADS-to-share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you.

A beneficial owner is any person or entity having a beneficial ownership interest in ADSs. A beneficial owner need not be the holder of the ADR evidencing such ADS. If a beneficial owner of ADSs is not an ADR holder, it must rely on the holder of the ADR(s) evidencing such ADSs in order to assert any rights or receive any benefits under the deposit agreement. A beneficial owner shall only be able to exercise any right or receive any benefit under the deposit agreement solely through the holder of the ADR(s) evidencing the ADSs owned by such beneficial owner. The arrangements between a beneficial owner of ADSs and the holder of the corresponding ADRs may affect the beneficial owner's ability to exercise any rights it may have.

An ADR holder shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by the ADRs registered in such ADR holder's name for all purposes under the deposit agreement and ADRs. The depositary's only notification obligations under the deposit agreement and the ADRs is to registered ADR holders. Notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs.

Unless certificated ADRs are specifically requested, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive that reflect your ownership of ADSs.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder or beneficial owner, you are not treated as a shareholder of ours and you do not have any shareholder rights. Cayman Island law governs shareholder rights. Because the depositary or its nominee is the shareholder of record for the ordinary shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder or of a beneficial owner. Such rights derive from the terms of the deposit agreement entered into among us, the depositary and all holders and beneficial owners from time to time of ADRs issued under the deposit agreement and, in the case of a beneficial owner, from the arrangements between the beneficial owner and the holder of the corresponding ADRs. The obligations of us and the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee is actually the registered owner of the ordinary shares, you must rely on it to exercise the rights of a shareholder on your behalf.

The deposit agreement, the ADRs and the ADSs are governed by and construed in accordance with the internal laws of the State of New York without giving effect to the application of the conflict of law principles thereof. Any claim brought against us by any holder or beneficial owner or on behalf of our company with regard to the internal affairs of our company, including the ability to bring such a claim, shall be governed by and construed in accordance with the laws of the Cayman Islands.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR that contains the terms of your ADSs. You can read a copy of the deposit agreement, which is filed as an exhibit to our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission.

Distributions on deposited securities, sales

How will I receive dividends and other distributions on the ordinary shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan to direct, manage and/or execute any public and/or private sale of securities and/or property under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary chargeable to holders of ADSs. All sales of securities will be handled by the depositary in accordance with its then current policies. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent. In all instances where the deposit agreement or an ADR refers to a “sale” (or words of similar import) of securities or property, the depositary may, but shall not be obligated, to effect any such sale unless the securities to be sold are listed and publicly traded on a securities exchange or there is a public market for the property to be sold. To the extent the securities are not so listed and publicly traded or there is no public market for the property so distributed by us: (1) the depositary shall, in the event the deposit agreement is terminated and the depositary holds deposited securities that are not listed and publicly traded after the termination date of the deposit agreement, act in accordance with the termination provisions of the deposit agreement and form of ADR in respect of such securities and property; and (2) in the event the depositary or its custodian receives a distribution other than cash, our ordinary shares and/or rights to acquire our ordinary shares, and such distribution consists of securities or property that are not distributed by the depositary the depositary will be deemed to have sold the aggregate number of securities and/or property so received for nominal value and shall have no obligation to distribute such securities or any proceeds from the deemed sale thereof to the ADR holders. Furthermore, in the event the depositary endeavors to make a sale of ordinary shares, other securities or property, such securities and/or property may be sold in a block sale or single lot transaction.

Except as stated below, the depositary will distribute as soon as reasonably practical such distributions to ADR holders in proportion to their interests in the following manner:

- **Cash.** The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (1) appropriate adjustments for taxes withheld, (2) such distribution being permissible or practicable with respect to certain registered ADR holders, and (3) deduction of the depositary’s and/or its agents’ fees and expenses in (A) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (B) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (C) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (D) making any sale by public or private means in any commercially reasonable manner. To the extent that any of the deposited securities is not or shall not be entitled, by reason of its date of issuance, or otherwise, to receive the full amount of such cash dividend, distribution, or net proceeds of sales, the depositary shall make appropriate adjustments in the amounts distributed to the ADR holders issued in respect of such deposited securities. To the extent we or the depositary shall be required to withhold and do withhold from any cash dividend, distribution or net proceeds from sales in respect of any deposited securities an amount on account of taxes, the amount distributed on the ADSs issued in respect of such deposited securities shall be reduced accordingly.

- To the extent the depositary determines in its reasonable discretion that it would not be permitted by applicable law, rule or regulation, or it would not otherwise be practicable, to convert foreign currency into U.S. dollars and distribute such U.S. dollars to some or all of the ADR holders entitled thereto, the depositary may in its discretion distribute some or all of the foreign currency received by the depositary as it deems permissible and practicable to, or retain and hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the ADR holders entitled to receive the same. To the extent the depositary retains and holds any cash, foreign currency, securities or other property as permitted under the deposit agreement, any and all fees, charges and expenses related to, or arising from, the holding thereof shall be paid from such cash, foreign currency, securities or other property, or the net proceeds from the sale thereof, thereby reducing the amount so held. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*
- *Shares.* In the case of a distribution in ordinary shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such ordinary shares. Only whole ADSs will be issued. Any ordinary shares that would result in fractional ADSs will be sold and the net proceeds of the public or private sales of such will be distributed in the same manner as cash to the ADR holders entitled thereto.
- *Rights to receive additional shares.* In the case of a distribution of rights to subscribe for additional ordinary shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not timely furnish such evidence, the depositary may:
 - (i) sell such rights if practicable and distribute the net proceeds of the public or private sales of such rights in the same manner as cash to the ADR holders entitled thereto; or
 - (ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

We have no obligation to file a registration statement under the Securities Act in order to make any rights available to ADR holders.

- *Other distributions.* In the case of a distribution of securities or property other than those described above, the depositary may either (1) distribute such securities or property in any manner it deems equitable and practicable or (2) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds of public or private sales in the same way it distributes cash.
- *Elective distributions.* In the case of a dividend payable at the election of our shareholders in cash or in additional ordinary shares, we will notify the depositary at least 30 days prior to the proposed distribution stating whether or not we wish such elective distribution to be made available to ADR holders. The depositary shall make such elective distribution available to ADR holders only if (1) we shall have timely requested that the elective distribution is available to ADR holders, (2) the depositary shall have determined that such distribution is reasonably practicable and (3) the depositary shall have received satisfactory documentation within the terms of the deposit agreement including any legal opinions of counsel that the depositary in its reasonable discretion may request. If the above conditions are not satisfied, the depositary shall, to the extent permitted by law, distribute to the ADR holders, on the basis of the same determination as is made in the local market in respect of the ordinary shares for which no election is made, either (x) cash or (y) additional ADSs representing such additional ordinary shares. If the above conditions are satisfied, the depositary shall establish procedures to enable ADR holders to elect the receipt of the proposed dividend in cash or in additional ADSs. There can be no assurance that ADR holders or beneficial owners of ADSs generally, or any ADR holder or beneficial owner of ADSs in particular, will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

If the depositary determines in its reasonable discretion that any distribution described above is not practicable with respect to any or all ADR holders, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of some or all of any cash, foreign currency, securities or other property (or appropriate documents evidencing the right to receive some or all of any such cash, foreign currency, security or other property), and/or it may retain some or all of such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items. To the extent the depositary does not reasonably believe it will be permitted by applicable law, rule or regulation to convert foreign currency into U.S. dollars and distribute such U.S. dollars to some or all of the ADR holders, the depositary may in its discretion distribute some or all of the foreign currency received by the depositary to, or hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the ADR holders entitled to receive the same. To the extent the depositary holds such foreign currency, any and all costs and expenses related to, or arising from, the holding of such foreign currency shall be paid from such foreign currency thereby reducing the amount so held.

Any U.S. dollars will be paid via wire transfer and/or distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it fails to determine that any distribution or action is lawful or reasonably practicable.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, ordinary shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. All purchases and sales of securities will be handled by the depositary in accordance with its then current policies, which are currently set forth on the "Disclosures" page (or successor page) of www.adr.com (as updated by the depositary from time to time, "ADR.com").

Deposit, withdrawal and cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance.

Ordinary shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of "JPMorgan Chase Bank, N.A., as depositary for the benefit of holders of ADRs" or in such other name as the depositary shall direct.

The custodian will hold all deposited ordinary shares for the account and to the order of the depositary, in each case for the benefit of ADR holders, to the extent not prohibited by law. ADR holders and beneficial owners thus have no direct ownership interest in the ordinary shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited ordinary shares. The deposited ordinary shares and any such additional items are referred to as "deposited securities."

Deposited securities are not intended to, and shall not, constitute proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in deposited securities is intended to be, and shall at all times during the term of the deposit agreement continue to be, vested in the beneficial owners of the ADSs representing such deposited securities. Notwithstanding anything else contained herein, in the deposit agreement, in the form of ADR and/or in any outstanding ADSs, the depositary, the custodian and their respective nominees are intended to be, and shall at all times during the term of the deposit agreement be, the record holder(s) only of the deposited securities represented by the ADSs for the benefit of the ADR holders. The depositary, on its own behalf and on behalf of the custodian and their respective nominees, disclaims any beneficial ownership interest in the deposited securities held on behalf of the ADR holders.

Upon each deposit of ordinary shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such ADR holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, subject to the provisions of or governing our ordinary shares (including, without limitation, our governing documents and all applicable laws, rules and regulations), the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying ordinary shares to you or upon your written order. Delivery of deposited securities in certificated form will be made at the custodian's office (or from the custodian to the extent dematerialized). At your risk, expense and request, the depositary may deliver deposited securities (including any certificates therefor) at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Record dates

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities,
- to give instructions for the exercise of voting rights,
- to pay any fees assessed by, or owing to, the depositary for administration of the ADR program and for any expenses as provided for in the ADR, or
- to receive any notice or to act or be obligated in respect of other matters,

all subject to the provisions of the deposit agreement.

Voting rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the ordinary shares which underlie your ADSs. As soon as practicable after receipt from us of notice of any meeting at which the holders of ordinary shares are entitled to vote, or of our solicitation of consents or proxies from holders of ordinary shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement, provided that if the depositary receives a written request from us in a timely manner and at least thirty (30) days prior to the date of such vote or meeting, the depositary shall, at our expense, distribute to the registered ADR holders a “voting notice” stating (1) final information particular to such vote and meeting and any solicitation materials, (2) that each ADR holder on the record date set by the depositary will, subject to any applicable provisions of the laws of the Cayman Islands, be entitled to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the deposited securities represented by the ADSs evidenced by such ADR holder’s ADRs and (3) the manner in which such instructions may be given or deemed given in accordance with the applicable provisions of deposit agreement, including instructions for giving a discretionary proxy to a person designated by us. Each ADR holder shall be solely responsible for the forwarding of voting notices to the beneficial owners of ADSs registered in such ADR holder’s name. There is no guarantee that ADR holders and beneficial owners generally or any holder or beneficial owner in particular will receive the notice described above with sufficient time to enable such ADR holder or beneficial owner to return any voting instructions to the depositary in a timely manner.

Following actual receipt by the ADR department responsible for proxies and voting of ADR holders’ instructions (including, without limitation, instructions of any entity or entities acting on behalf of the nominee for The Depositary Trust Company, or DTC), the depositary shall, in the manner and on or before the time established by the depositary for such purpose, endeavor to vote or cause to be voted the deposited securities represented by the ADSs evidenced by such ADR holders’ ADRs in accordance with such instructions insofar as practicable and permitted under the provisions of or governing deposited securities.

To the extent that (A) we have provided the depositary with at least 35 days’ notice of the proposed meeting, (B) the voting notice will be received by all holders and beneficial owners no less than 10 days prior to the date of the meeting and/or the cut-off date for the solicitation of consents, and (C) the depositary does not receive instructions on a particular agenda item from a holder (including, without limitation, any entity or entities acting on behalf of the nominee for DTC) in a timely manner, such holder shall be deemed, and, pursuant to the deposit agreement, the depositary is instructed to deem such holder, to have instructed the depositary to give a discretionary proxy for such agenda item(s) to a person designated by us to vote the deposited securities represented by the ADSs for which actual instructions were not so given by all such holders on such agenda item(s), provided that no such instruction shall be deemed given and no discretionary proxy shall be given unless (1) we inform the depositary in writing that (a) we wish such proxy to be given with respect to such agenda item(s), (b) there is no substantial opposition existing with respect to such agenda item(s) and (c) such agenda item(s), if approved, would not materially or adversely affect the rights of holders of ordinary shares, and (2) the depositary has obtained an opinion of counsel, in form and substance satisfactory to the depositary, confirming that (i) the granting of such discretionary proxy does not subject the depositary to any reporting obligations in the Cayman Islands, (ii) the granting of such proxy will not result in a violation of the laws, rules, regulations or permits of the Cayman Islands, (iii) the voting arrangement and deemed instruction as contemplated in the deposit agreement will be given effect under the laws, rules and regulations of the Cayman Islands, and (iv) the granting of such discretionary proxy will not under any circumstances result in the ordinary shares represented by the ADSs being treated as assets of the depositary under the laws, rules or regulations of the Cayman Islands.

The depositary may from time to time access information available to it to consider whether any of the circumstances described in 1(b) or 1(c) the paragraph above exist, or request additional information from us in respect thereto. By taking any such action, the depositary shall not in any way be deemed or inferred to have been required, or have had any duty or responsibility (contractual or otherwise), to monitor or inquire whether any of the circumstances described above existed. In addition to the limitations provided for in the deposit agreement, holders and beneficial owners are advised and agree that (a) the depositary will rely fully and exclusively on us to inform it of any of the circumstances set forth above, and (b) neither the depositary, the custodian nor any of their respective agents shall be obliged to inquire or investigate whether any of the circumstances described in 1(b) or 1(c) the paragraph above exist and/or whether we complied with our obligation to timely inform the depositary of such circumstances. Neither the depositary, the custodian nor any of their respective agents shall incur any liability to holders or beneficial owners (i) as a result of our failure to determine that any of the circumstances described in 1(b) or 1(c) the paragraph above exist or our failure to timely notify the depositary of any such circumstances or (ii) if any agenda item which is approved at a meeting has, or is claimed to have, a material or adverse effect on the rights of holders of ordinary shares. Because there is no guarantee that holders and beneficial owners will receive the notices described above with sufficient time to enable such holders or beneficial owners to return any voting instructions to the depositary in a timely manner, holders and beneficial owners may be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us in such circumstances, and neither the depositary, the custodian nor any of their respective agents shall incur any liability to holders or beneficial owners in such circumstances.

Under Cayman Islands law and our A&R Articles, each as currently in effect, voting at any meeting of our shareholders is by show of hands unless a poll is (before or on the declaration of the results of the show of hands or on the withdrawal of any other demand for a poll) demanded. In the event that voting on any resolution or matter is conducted on a show of hands basis, the depositary will refrain from voting and the voting instructions received by the depositary shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so.

ADR holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. For instructions to be valid, the ADR department of the depositary that is responsible for proxies and voting must receive them in the manner and on or before the time specified, notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion in respect of deposited securities. The depositary and its agents will not be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given or deemed to be given in accordance with the applicable provisions of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy or deemed to have been instructed to grant a discretionary proxy pursuant to the applicable provisions of the deposit agreement, or for the effect of any such vote.

Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by any law, rule or regulation, or by the rules, regulations or requirements of any stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of or solicitation of consents or proxies from holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such ADR holders with or otherwise publicizes to such ADR holders instructions on how to retrieve such materials or receive such materials upon request (*i.e.*, by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and other communications

Will ADR holders be able to view our reports?

The deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities, are available for inspection by ADR holders at the offices of the depositary in the United States, on the SEC's internet website or upon request to the depositary (which request may be refused by the depositary at its discretion).

Additionally, if we make (i) any communications available to holders of our ordinary shares or any securities regulatory authority or stock exchange that could require, or result in, the depositary taking or planning to take any action pursuant to the deposit agreement or (ii) any communication that reasonably could require the depositary to take, or plan to take, action pursuant to the deposit agreement, we will furnish copies thereof (or English translations or summaries) to the depositary and the depositary will distribute the same to registered ADR holders.

Fees and expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of ordinary share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADSs are cancelled or reduced for any other reason, a fee of up to US\$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional fees, charges and expenses shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of up to US\$0.05 per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of up to US\$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- an amount for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian, as well as charges and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law, rule or regulation relating to foreign investment) in connection with the servicing of the shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee of up to US\$0.05 per ADS held for the direct or indirect distribution of securities (other than ADSs or rights to purchase additional ADSs) or the net cash proceeds from the public or private sale of such securities, regardless of whether any such distribution and/or sale is made by, for, or received from, or (in each case) on behalf of, the depositary, us and/or any third party (which fee may be assessed against ADR holders as of a record date set by the depositary);
- stock transfer or other taxes and other governmental charges;
- a transaction fee per cancellation request (including any cancellation request made through SWIFT, facsimile transmission or any other method of communication) as disclosed on the "Disclosures" page (or successor page) of www.adr.com (as updated by the depositary from time to time, "ADR.com") and any applicable delivery expenses (which are payable by such persons or ADR holders);
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within the banking division of the depositary, or the Bank, and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to a foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the “Disclosures” page (or successor page) of ADR.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, ADR holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other fees, charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to charge and receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

The depositary anticipates reimbursing us for certain expenses incurred by us that are related to the establishment and maintenance of the ADR program upon such terms and conditions as we and the depositary may agree from time to time. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary may also agree to reduce or waive certain fees that would normally be charged on ADSs issued to or at the director of, or otherwise held by, us and/or certain holders and beneficial owners and holders and beneficial owners of ordinary shares of ours. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing ordinary 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 will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of taxes

ADR holders and/or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon such tax or other governmental charge shall be paid by the ADR holder thereof to the depositary and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect of such tax or other governmental charge. Notwithstanding the depositary's right to seek payment from current or former ADR holders and beneficial owners, each ADR holder and beneficial owner, and each prior ADR holder and beneficial owner, by holding or owning, or having held or owned, an ADR or an interest in ADSs acknowledges and agrees that the depositary has no obligation to seek payment of amounts owing from any current or prior beneficial owner. If an ADR holder owes any tax or other governmental charge, the depositary may (1) deduct the amount thereof from any cash distributions, or (2) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case, the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of ADRs or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto. Neither we nor the depositary nor any of the depositary's or our respective agents shall be liable to holders or beneficial owners of the ADSs and ADRs for failure of any holders or beneficial owners to comply with applicable tax laws, rules and/or regulations.

To the extent not prohibited by law, rule, regulation, fiduciary duty, contractual or confidential obligation or otherwise, the depositary will forward to us such information in the depositary's possession from the transfer records maintained by the depositary in accordance with the depositary's policies and procedures as we may reasonably request in writing to enable us to file any reports required to be filed by us with governmental authorities or agencies to comply with applicable laws; provided, however, that the depositary will have no liability for the accuracy of any such information and will, in connection with any such accuracy and inaccuracy, not be required to incur or become subject to any liability, cost or expense and will be indemnified by us in connection therewith.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained, which obligations shall survive any transfer or surrender of ADSs or the termination of the deposit agreement.

Reclassifications, recapitalizations and mergers

If we take certain actions that affect the deposited securities, including (1) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (2) any distributions of ordinary shares or other property not made to holders of ADRs or (3) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell by public or private sale any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

Amendment and termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least 30 days' notice of any amendment that imposes or increases any fees on a per ADS basis, charges or expenses (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, a transaction fee per cancellation request (including any cancellation request made through SWIFT, facsimile transmission or any other method of communication), applicable delivery expenses or other such fees, charges or expenses), or otherwise prejudices any substantial existing right of ADR holders or beneficial owners. If an ADR holder or beneficial owner continues to hold an ADR or ADRs, or an interest therein, after being so notified, such ADR holder and any beneficial owner are deemed to agree to such amendment and to be bound by the deposit agreement as so amended. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

Any amendments or supplements that (1) are reasonably necessary (as agreed by us and the depositary) in order for (A) the ADSs to be registered on Form F-6 under the Securities Act, or (B) the ADSs or ordinary shares to be traded solely in electronic book-entry form and (2) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders or beneficial owners. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations that would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the form of ADR (and all outstanding ADRs) at any time in accordance with such changed laws, rules or regulations. Such amendment or supplement to the deposit agreement in such circumstances may become effective before a notice of such amendment or supplement is given to ADR holders or within any other period of time as required for compliance.

Notice of any amendment to the deposit agreement or form of ADR shall not need to describe in detail the specific amendments effectuated thereby, and failure to describe the specific amendments in any such notice shall not render such notice invalid, provided, however, that, in each such case, the notice given to the ADR holders identifies a means for ADR holders and beneficial owners to retrieve or receive the text of such amendment (*i.e.*, upon retrieval from the SEC's, the depositary's or our website or upon request from the depositary).

How may the deposit agreement be terminated?

The depositary may at any time, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (1) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered ADR holders unless a successor depositary shall not be operating under the deposit agreement within 60 days of the date of such resignation, and (2) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 60th day after our notice of removal was first provided to the depositary. Notwithstanding anything to the contrary in the deposit agreement, the depositary may terminate the deposit agreement (A) without notifying us, but subject to giving 30 days' notice to the ADR holders, under the following circumstances: (i) in the event of our bankruptcy, liquidation proceedings or insolvency, (ii) if the ADRs are delisted from a "national securities exchange" (that has registered with the Commission under Section 6 of the Exchange Act), (iii) if we effect (or will effect) a redemption of all or substantially all of the deposited securities, or a cash or share distribution representing a return of all or substantially all of the value of the deposited securities, (iv) there are no deposited securities with respect to ADSs remaining, including if the deposited securities are cancelled, or the deposit securities have been deemed to have no value, or (v) there occurs a merger, consolidation, sale of assets or other transaction as a result of which securities or other property are delivered in exchange for or in lieu of deposited securities, and (B) immediately without prior notice to us, any ADR holder or beneficial owner or any other person if (i) required by any law, rule or regulation relating to sanctions by any governmental authority or body, (ii) the depositary would be subject to liability under or pursuant to any law, rule or regulation, or (iii) required by any governmental authority or body, in each case under (b) as determined by the depositary in its reasonable discretion.

If our ordinary shares are not listed and publicly traded on a stock exchange or in a securities market as of the date so fixed for termination or if, for any reason, the depositary does not sell the deposited securities, then after such date fixed for termination, the depositary shall use its reasonable efforts to ensure that the ADSs cease to be eligible for settlement within DTC and that neither DTC nor any of its nominees shall thereafter be an ADR holder. At such time as the ADSs cease to be DTC eligible and/or neither DTC nor any of its nominees is an ADR holder, to the extent we are not, to the depositary's knowledge, insolvent or in bankruptcy or liquidation, the depositary shall (A) cancel all outstanding ADRs; (B) request DTC to provide the depositary with information on those holding ADSs through DTC and, upon receipt thereof, revise the ADR register to reflect the information provided by DTC; (C) instruct its custodian to deliver all deposited securities to us, a subsidiary or affiliate of ours (the company representative) or an independent trust company engaged by us (the trustee) to hold those deposited securities in trust for the beneficial owners of the ADRs if we are not permitted to hold any of the deposited securities under applicable law and/or we have directed the depositary to deliver such deposited securities to the company representative or trustee along with a stock transfer form and/or such other instruments of transfer covering such deposited securities as are needed under applicable law, in either case referring to the names set forth on the ADR register and (D) provide us with a copy of the ADR register.

Upon receipt of any instrument of transfer covering such deposited securities and the ADR Register, we have agreed that we will, to the extent not prohibited by any law, rule or regulation, approve the transfer of the deposited securities previously represented by their ADRs to the persons listed on the ADR register (as applicable), procure the relevant updates to our register of members to reflect the transfer of the deposited securities previously represented by their ADRs to the persons listed on the ADR register (as applicable) and provide the depositary with a certified copy of the updated register of our shareholders.

To the extent the depositary reasonably believes that we are insolvent, or if we are in receivership, have filed for bankruptcy and/or are otherwise in restructuring, administration or liquidation, and in any such case the deposited securities are not listed and publicly traded on a securities exchange after the termination date, or if, for any reason, the depositary believes it is not able to or cannot practicably sell the deposited securities promptly and without undue effort, the deposited securities shall be deemed to have no value (and such holder shall be deemed to have instructed the depositary that the deposited securities have no value). The depositary may (and, by holding an ADR or an interest therein, all holders irrevocably consent and agree that the depositary may) instruct its custodian to deliver all deposited securities to us (acting, as applicable by an administrator, receiver, administrative receiver, liquidator, provisional liquidator, restructuring officer, interim restructuring officer, trustee, controller or other entity overseeing the bankruptcy, insolvency, administration, restructuring or liquidation process) and notify us that the deposited ordinary shares are surrendered for no consideration. The deposit agreement requires us, subject to applicable law, to promptly accept the surrender of the deposited ordinary shares for no consideration and deliver to the depositary a written notice confirming (A) the acceptance of the surrender of the deposited securities for no consideration and (B) the cancellation of such deposited ordinary shares. Promptly after notifying us that the deposited ordinary shares are surrendered for no consideration and irrespective of whether we have complied with the immediately preceding sentence, the depositary shall notify ADR holders that their ADSs have been cancelled with no consideration being payable to such ADR holders.

Upon the depositary's compliance with the provisions of any of the above three paragraphs, the depositary and its agents shall be discharged from all, and cease to have any, obligations under the deposit agreement and the ADRs.

Notwithstanding anything to the contrary, in connection with any termination in accordance with the provisions in this section, the depositary may, in its sole discretion and without notice to us, establish an unsponsored American depositary share program (on such terms as the depositary may determine) for our ordinary shares and make available to ADR holders a means to withdraw the ordinary shares represented by the ADSs issued under the deposit agreement and to direct the deposit of such ordinary shares into such unsponsored American depositary share program, subject, in each case, to receipt by the depositary, at its discretion, of the fees, charges and expenses provided for in the ADR and the fees, charges and expenses applicable to the unsponsored American depositary share program; provided that the depositary agrees that we will have no liability for the establishment of such unsponsored American depositary share program.

If our ordinary shares are listed and publicly traded on a securities exchange and the depositary believes that it is able, permissible and practicable to sell the deposited securities without undue effort, then the depositary may endeavor to publicly or privately sell (as long as it may lawfully do so) the deposited securities, which sale may be effected in a block sale/single lot transaction and, after the settlement of such sale(s), to the extent legally permissible and practicable, distribute or hold in an account (which may be a segregated or unsegregated account) the net proceeds of such sale(s), less any amounts owing to the depositary (including, without limitation, cancellation fees), together with any other cash then held by it under the deposit agreement, in trust, without liability for interest, for the pro rata benefit of the holders entitled thereto. After making such sale, the depositary shall be discharged from all obligations in respect of the deposit agreement and the ADRs, except to account for such net proceeds and other cash.

Limitations on obligations and liability

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders, beneficial owners and others

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs, we or the depositary or its custodian may require:

- payment with respect thereto of (1) any stock transfer or other tax or other governmental charge, (2) any stock transfer or registration fees in effect for the registration of transfers of ordinary shares or other deposited securities upon any applicable register and (3) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (1) the identity of any signatory and genuineness of any signature and (2) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial or other ownership of, or interest in, any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement or as the depositary believes are required, necessary or advisable in order to comply with applicable laws, rules and regulations.

The issuance of ADRs, the acceptance of deposits of ordinary shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of ordinary shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed required, necessary or advisable by the depositary for any reason provided that the ability to withdraw ordinary shares may only be limited under the following circumstances: (1) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends, (2) the payment of fees, taxes, and similar charges, and (3) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities. The depositary may close the ADR register (and/or any portion thereof) at any time or from time to time when deemed expedient by it. Additionally, at our reasonable request, the depositary may close the issuance book portion of the ADR register solely in order to enable us to comply with applicable law; provided that the depositary will have no liability and will be indemnified by us in such event.

The deposit agreement expressly limits the obligations and liability of the depositary, the depositary's custodian or ourselves and each of our and their respective directors, officers, employees, agents and affiliates, provided, however, that no provision of the deposit agreement is intended to constitute a waiver or limitation of any rights that ADR holders or beneficial owners may have under the Securities Act or the Exchange Act, to the extent applicable. The deposit agreement provides that each of us, the depositary and our respective directors, officers, employees, agents and affiliates will:

- incur or assume no liability (including, without limitation, to ADR holders or beneficial owners) if any present or future law, rule, regulation, fiat, order or decree of the United States, the Cayman Islands, the PRC or any other country or jurisdiction, or of any governmental or regulatory authority or any securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our memorandum and articles of association, any act of God, war, terrorism, epidemic, pandemic, nationalization, expropriation, currency restrictions, extraordinary market conditions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, cyber, ransomware or malware attack, computer failure or circumstance our, the depositary's or our respective directors', officers', employees', agents' or affiliates' direct and immediate control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by any such party (including, without limitation, voting);
- incur or assume no liability (including, without limitation, to ADR holders or beneficial owners) by reason of any non-performance or delay, caused as aforesaid, in the performance of any act or things which by the terms of the deposit agreement it is provided shall or may be done or performed or any exercise or failure to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- incur or assume no liability (including, without limitation, to holders or beneficial owners) if it performs its obligations specifically set forth in the deposit agreement and ADRs without gross negligence or willful misconduct;
- in the case of the depositary and its agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs;
- in the case of us and our agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs, which in our or our agents' opinion, as the case may be, may involve us in expense or liability, unless indemnity satisfactory to us or our agent, as the case may be, against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be requested;
- not be liable (including, without limitation, to ADR holders or beneficial owners) for any action or inaction by it in reliance upon the advice of or information from any legal counsel, any accountant, any person presenting ordinary shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information and/or, in the case of the depositary, from us; or
- be able to rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given by the proper party or parties.

The depositary shall not be a fiduciary or have any fiduciary duty to ADR holders or beneficial owners.

The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered ADR holder has incurred liability directly as a result of the custodian having (1) committed fraud or willful misconduct in the provision of custodial services to the depositary or (2) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary and the custodian(s) may use third party delivery services and providers of information regarding matters such as, but not limited to, pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide services such as, but not limited to, attendance at any meetings of security holders of our company. Although the depositary and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third-party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services.

The depositary has no obligation to inform ADR holders or beneficial owners about the requirements of the laws, rules or regulations or any changes therein or thereto of the Cayman Islands, the PRC, the United States or any other country or jurisdiction or of any governmental or regulatory authority or any securities exchange or market or automated quotation system.

Additionally, none of the depositary, the custodian or us, or any of their or our respective directors, officers, employees, agents or affiliates shall be liable for the failure by any registered holder of ADRs or beneficial owner to obtain the benefits of credits or refunds of non-U.S. tax paid against such ADR holder's or beneficial owner's income tax liability. The depositary is under no obligation to provide the ADR holders and beneficial owners, or any of them, with any information about our tax status. None of us, the depositary, the custodian or any of our or their respective directors, officers, employees, agents or affiliates shall incur any liability for any tax or tax consequences that may be incurred by registered ADR holders or beneficial owners on account of their ownership or disposition of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy pursuant to the terms of the deposit agreement, or for the effect of any such vote. The depositary shall endeavor to effect any sale of securities or other property and any conversion of currency, securities or other property, in each case as is referred to or contemplated in the deposit agreement or the form of ADR, in accordance with the depositary's normal practices and procedures under the circumstances applicable to such sale or conversion, but shall have no liability (in the absence of its own willful default or gross negligence or that of its agents, officers, directors or employees) with respect to the terms of any such sale or conversion, including the price at which such sale or conversion is effected, or if such sale or conversion shall not be practicable, or shall not be believed, deemed or determined to be practicable by the depositary. Specifically, the depositary shall not have any liability for the price received in connection with any public or private sale of securities (including, without limitation, for any sale made at a nominal price), the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale. The depositary shall not incur any liability in connection with or arising from any failure, inability or refusal by us or any other party, including any share registrar, transfer agent or other agent appointed by us, the depositary or any other party, to process any transfer, delivery or distribution of cash, ordinary shares, other securities or other property, including without limitation upon the termination of the deposit agreement, or otherwise to comply with any provisions of the deposit agreement that are applicable to it. The depositary may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be liable for 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. Neither the depositary nor us, nor any of their or our respective agents shall be liable to the other for any indirect, special, punitive or consequential damages (excluding reasonable fees and expenses of counsel) or lost profits, in any form, or Special Damages, incurred by any of them or us, or liable to any other person or entity (including, without limitation, holders and beneficial owners) for any Special Damages, or any fees or expenses of counsel in connection therewith, whether or not foreseeable and regardless of the type of action in which such a claim may be brought; provided, however, that (i) notwithstanding the foregoing, the depositary and its agents will be entitled to legal fees and expenses in defending against any claim for Special Damages and (ii) to the extent Special Damages arise from or out of a claim brought by a third party (including, without limitation, holders and beneficial owners) against the depositary or any of its agents, the depositary and its agents shall be entitled to full indemnification from us for all such Special Damages, and reasonable fees and expenses of counsel in connection therewith, unless such Special Damages are found to have been a direct result of the gross negligence or willful misconduct of the depositary.

The depositary and its agents may own and deal in any class of securities of ours and our affiliates and in ADSs.

Disclosure of interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of, or interest in, deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you as ADR holders or beneficial owners agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof.

Books of depositary

The depositary or its agent maintains a register for the registration, registration of transfer, combination, split-up, substitution and cancellation of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other ADR holders in the interest of our business or a matter relating to the deposit agreement. Such register (and/or any portion thereof) may be closed at any time or from time to time, when deemed expedient by the depositary.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Appointment

In the deposit agreement, each registered holder of ADRs and each beneficial owner, upon acceptance of any ADSs or ADRs (or any interest in any of them) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs,
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof; and
- acknowledge and agree that (1) nothing in the deposit agreement or any ADR shall give rise to a partnership or joint venture among the parties thereto, nor establish a fiduciary or similar relationship among such parties, (2) the depositary, its divisions, branches and affiliates, and their respective agents, may from time to time be in the possession of non-public information about us, ADR holders, beneficial owners and/or their respective affiliates, (3) the depositary and its divisions, branches and affiliates may at any time have multiple banking relationships with us, ADR holders, beneficial owners and/or the affiliates of any of them, (4) the depositary and its divisions, branches and affiliates may, from time to time, be engaged in transactions in which parties adverse to us, ADR holders, or beneficial owners may have interests, (5) nothing contained in the deposit agreement or any ADR(s) shall (A) preclude the depositary or any of its divisions, branches or affiliates from engaging in any such transactions or establishing or maintaining any such relationships, or (B) obligate the depositary or any of its divisions, branches or affiliates to disclose any such transactions or relationships or to account for any profit made or payment received in any such transactions or relationships, (6) the depositary shall not be deemed to have knowledge of any information held by any branch, division or affiliate of the depositary and (7) notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs. For all purposes under the deposit agreement and the ADRs, the ADR holders thereof shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by such ADRs.

Consent to jurisdiction

In the deposit agreement, we have appointed an agent for service of process on our behalf. Any action based on the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby may be instituted by the depositary against us in the state or federal courts in New York, New York or any competent court in the Cayman Islands, the United States and/or any other court of competent jurisdiction.

Under the deposit agreement, by holding or owning an ADR or ADS or an interest therein, holders and beneficial owners each irrevocably agree that (1) any legal suit, action or proceeding against or involving holders or beneficial owners brought by us or the depositary, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, may be instituted in a state or federal court in New York, New York, and by holding or owning an ADR or ADS or an interest therein each irrevocably waives any objection that it may now or hereafter have to the laying of venue of any such proceeding, and irrevocably submits to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding and (2) any legal suit, action or proceeding against or involving us and/or the depositary brought by holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, including, without limitation, claims under the Securities Act and the Exchange Act, may only be instituted only in the United States District Court for the Southern District of New York (or in the state courts of New York County in New York if either (a) the United States District Court for the Southern District of New York lacks subject matter jurisdiction over the particular dispute or (b) the designation of the United States District Court for the Southern District of New York as the exclusive forum for the particular dispute is, or becomes, invalid, illegal or unenforceable). In the deposit agreement each holder and beneficial owner irrevocably waives any objection which it may at any time have to the laying of venue of any such proceeding, and irrevocably submits to the jurisdiction of such courts in any such suit, action or proceeding. Additionally, by holding or owning an ADR or ADS or an interest therein, holders and beneficial owners acknowledge and agree that they will not be able to commence or pursue any legal suit, action or proceeding against the depositary or its agents in any jurisdiction other than as described in this paragraph.

Notwithstanding anything in the deposit agreement to the contrary, by directly or indirectly holding or owing an ADR or ADS or an interest therein, holders and beneficial owners each agree that the depositary may, in its sole discretion, elect to institute any dispute, suit, action, controversy, claim or proceeding directly or indirectly based on, arising out of or relating to the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, including without limitation any question regarding its or their existence, validity, interpretation, performance or termination against any other party or parties, by having such dispute referred to and finally resolved by an arbitration; provided, however, to the extent there are specific federal securities law violation aspects to any claims against us and/or the depositary, such specific, and only such specific, claims may be brought by any holder or beneficial owner in the United States District Court for the Southern District of New York (or in the state courts of New York County in New York if either (i) the United States District Court for the Southern District of New York lacks subject matter jurisdiction over the particular dispute or (ii) the designation of the United States District Court for the Southern District of New York as the exclusive forum for the particular dispute is, or becomes, invalid, illegal or unenforceable) and all other aspects, claims, disputes, legal suits, actions and/or proceedings brought by such holder or beneficial owner, including those brought along with, or in addition to, federal securities law violation claims, would be referred to, or remain in arbitration. Any such arbitration shall, at the depositary's election, be conducted either in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association or in Hong Kong following the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL) with the Hong Kong International Arbitration Centre serving as the appointing authority and the language of any such arbitration shall be English. In all cases, the fees of the arbitrators and other costs incurred by the parties in connection with such arbitration shall be paid by the party (or parties) that is (or are) unsuccessful in such arbitration. Holders and beneficial owners shall not be entitled to join or consolidate disputes by or against others in any arbitration, or to include in any arbitration any dispute as a representative or member of a class, or act in any arbitration in the interest of the general public or in a private attorney general capacity.

Jury trial waiver

In the deposit agreement, each party thereto (including, for the avoidance of doubt, each holder and beneficial owner of, and/or holder of interests in, ADSs or ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of, based on or relating in any way to the ordinary shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory), including any claim under the U.S. federal securities laws.

If we or the depositary were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a trial by jury. The waiver to right to a trial by jury in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of our or the depositary's compliance with any provisions of U.S. federal securities laws or the rules and regulations promulgated thereunder.

Conversion between ordinary shares and ADSs

Dealings and settlement of ordinary shares in Hong Kong

Dealings in our ordinary shares on the HKEx are conducted in Hong Kong dollars. Our ordinary shares are traded on the HKEx in board lots of 100 ordinary shares. The transaction costs of dealings in our ordinary shares on the HKEx include:

- Hong Kong Stock Exchange trading fee of 0.005% of the consideration of the transaction, charged to each of the buyer and seller;
- SFC transaction levy of 0.0027% of the consideration of the transaction, charged to each of the buyer and seller;
- Accounting and Financial Reporting Council transaction levy of 0.00015% of the consideration of the transaction, charged to each of the buyer and seller;
- Trading tariff of HK\$0.50 on each and every purchase or sale transaction. The decision on whether or not to pass the trading tariff onto investors is at the discretion of brokers;
- Transfer deed stamp duty of HK\$5.00 per transfer deed (if applicable), payable by the seller;
- Ad valorem stamp duty at a total rate of 0.2% of the value of the transaction, with 0.1% payable by each of the buyer and the seller;
- Stock settlement fee, which is currently 0.002% of the gross transaction value, subject to a minimum fee of HK\$2.00 and a maximum fee of HK\$100.00 per side per trade;
- Brokerage commission, which is freely negotiable with the broker (other than brokerage commissions for IPO transactions which are currently set at 1% of the subscription or purchase price and will be payable by the person subscribing for or purchasing the securities); and
- Charge by the Hong Kong share registrar between HK\$2.50 to HK\$20, depending on the speed of service (or such higher fee as may from time to time be permitted under the Hong Kong Listing Rules), for each transfer of ordinary shares from one registered owner to another, each share certificate canceled or issued by it and any applicable fee as stated in the share transfer forms used in Hong Kong.

Investors must settle their trades executed on the HKEx through their brokers directly or through custodians. For an investor who has deposited his/her ordinary shares in his/her stock account or in his/her designated CCASS (“Central Clearing and Settlement System”) Participant’s stock account maintained with CCASS, settlement will be effected in CCASS in accordance with the General Rules of CCASS and CCASS Operational Procedures in effect from time to time. For an investor who holds the physical certificates, settlement certificates and the duly executed transfer forms must be delivered to his/her broker or custodian before the settlement date.

An investor may arrange with his/her broker or custodian on a settlement date in respect of his/her trades executed on the HKEx. Under the Hong Kong Listing Rules and the General Rules of CCASS and CCASS Operational Procedures in effect from time to time, the date of settlement must be the second business day (a day on which the settlement services of CCASS are open for use by CCASS Participants) following the trade date (T+2). For trades settled under CCASS, the General Rules of CCASS and CCASS Operational Procedures in effect from time to time provided that the defaulting broker may be compelled to compulsorily buy-in by HKSCC the day after the date of settlement (T+3), or if it is not practicable to do so on T+3, at any time thereafter. HKSCC may also impose fines from T+2 onwards.

The ADSs

The ADSs trade on Nasdaq. Dealings in the ADSs are conducted in U.S. Dollars. ADSs may be held either:

- Directly: (1) by having an ADR which is a certificate evidencing a specific number of ADSs, registered in the holder's name; or (2) by having uncertified ADSs in the direct registration system, which is a system administered by the DTC; or
- Indirectly, through a broker or other financial institution.

The depositary for the ADSs is JPMorgan Chase Bank, N.A., whose principal executive office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

Depositing ordinary shares trading in Hong Kong for delivery of ADSs

An investor who holds ordinary shares registered in Hong Kong and who wishes to receive delivery of ADSs to trade on Nasdaq must deposit or have his or her broker deposit the ordinary shares with the Depositary's Hong Kong custodian in exchange for ADSs. A deposit of ordinary shares trading in Hong Kong in exchange for ADSs involves the following procedures:

- If ordinary shares have been deposited with CCASS, the investor must transfer ordinary shares to the depositary's account with the custodian within CCASS by following the CCASS procedures for transfer and submit and deliver a duly completed and signed letter of transmittal to the custodian via his or her broker.
- If ordinary shares are held outside CCASS, the investor must arrange to deposit his or her ordinary shares into the CCASS for delivery to the depositary's account with the custodian within CCASS, and must submit and deliver a duly completed and signed letter of transmittal to the custodian via his or her broker.
- Upon payment of its fees and expenses, payment or net of the depositary's fees and expenses, and payment of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, if applicable, and subject in all cases to the terms of the deposit agreement, the depositary will register the corresponding number of ADSs in the name(s) requested by an investor and will deliver the ADSs to the designated DTC account of the person(s) designated by an investor or his or her broker if such ADSs are to be held in book-entry form through DTC's "Direct Registration System."

For ordinary shares deposited in CCASS, under normal circumstances, the above steps generally require two business days, provided that the investor has provided timely and complete instructions. For ordinary shares held outside CCASS in physical form, the above steps may take 14 business days, or more, to complete. Temporary delays may arise. For example, the transfer books of the depositary may from time to time be closed to ADS issuances. The investor will be unable to trade the ADSs until the procedures are completed.

Surrender of ADSs for delivery of ordinary shares trading in Hong Kong

An investor who holds ADSs and who wishes to receive ordinary shares that trade on the HKEx must cancel the ADSs the investor holds, withdraw ordinary shares from the ADS program and cause his or her broker or other financial institution to trade such ordinary shares on the HKEx.

An investor that holds ADSs indirectly through a broker or other financial institution should follow the procedure of the broker or financial institution and instruct the broker to arrange for cancellation of the ADSs and transfer of the underlying ordinary shares from the depositary's account with the custodian within the CCASS system to the investor's Hong Kong stock account. For investors holding ADSs directly, the following steps must be taken:

- To withdraw ordinary shares from the ADS program, an investor who holds ADSs may turn in such ADSs at the office of the depositary (and the applicable ADR(s) if the ADSs are held in certificated form), and send an instruction to cancel such ADSs to the depositary.
- Upon payment or net of its fees, payment of CCASS' fees and expenses, and payment of expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, if applicable, and subject in all cases to the terms of the deposit agreement, the depositary will instruct the custodian to deliver ordinary shares underlying the canceled ADSs to the CCASS account designated by an investor.
- If an investor prefers to receive ordinary shares outside CCASS, he or she must receive ordinary shares in CCASS first and then arrange for withdrawal from CCASS. Investors can then obtain a transfer form signed by HKSCC Nominees Limited (as the transferor) and register ordinary shares in their own names with the Hong Kong share registrar.

For ordinary shares to be received in CCASS, under normal circumstances, the above steps generally require two business days, provided that the investor has provided timely and complete instructions.

For ordinary shares to be received outside CCASS in physical form, the above steps may take 14 business days, or more, to complete. The investor will be unable to trade the ordinary shares on the HKEx until the procedures are completed.

Temporary delays may arise. For example, the transfer books of the depositary may from time to time be closed to ADS cancellations. In addition, completion of the above steps and procedures for delivery for ordinary shares in a CCASS account is subject to there being a sufficient number of ordinary shares on the Hong Kong share register to facilitate a withdrawal from the ADS program directly into the CCASS. We are not under any obligation to maintain or increase the number of ordinary shares on the Hong Kong share register to facilitate such withdrawals.

Depositary requirements

Before the depositary delivers ADSs or permits withdrawal of ordinary shares, the depositary may require:

- payment of all amounts required pursuant to the deposit agreement, including the issuance and cancellation fees therein, any stock transfer or other tax or other governmental charges and any stock transfer or registration fees in effect;
- production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with procedures it may establish, from time to time, consistent with the deposit agreement, including completion and presentation of transfer documents.

The depositary may refuse to deliver, transfer, or register issuances, transfers, and cancellations of ADSs generally when the transfer books of the depositary or our Hong Kong share registrar or Cayman Islands share registrar are closed or at any time if the depositary or we determine it advisable to do so, subject to such refusal complying with U.S. federal securities laws.

All costs attributable to the transfer of ordinary shares to effect a withdrawal from or deposit of ordinary shares into the ADS program will be borne by the investor requesting the transfer. In particular, holders of ordinary shares and ADSs should note that the Hong Kong share registrar will charge between HK\$2.50 to HK\$20, depending on the speed of service (or such higher fee as may from time to time be permitted under the Hong Kong Listing Rules), for each transfer of ordinary shares from one registered owner to another, each share certificate canceled or issued by it and any applicable fee as stated in the share transfer forms used in Hong Kong. In addition, holders of ordinary shares and ADSs must pay up to US\$5.00 per 100 ADSs (or portion thereof) for each issuance of ADSs and each cancellation of ADSs, as the case may be, in connection with the deposit of ordinary shares into, or withdrawal of ordinary shares from, the ADS program.

Ascentage Pharma Group International
(incorporation in the Cayman Islands with limited liability)

POST IPO SHARE OPTION SCHEME
(Adopted on September 28, 2019 and amended on May 19, 2025)

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Ascentage Pharma Group International
(Incorporated in the Cayman Islands with limited liability)

POST IPO SHARE OPTION SCHEME

1. DEFINITIONS

1.1 In this Scheme, except where the context otherwise requires, the following words and expressions have the following meanings:–

“**Acceptance Date**” means the date upon which an Offer must be accepted by the relevant Eligible Participant, being a date not later than 28 days after the Offer Date;

“**Adoption Date**” means September 28, 2019, the date on which this Scheme is conditionally adopted by an ordinary resolution of the Shareholders, and not being the Amendment Date for the avoidance of doubt;

“**Amendment Date**” means May 19, 2025, being the date on which the amended and restated Scheme is adopted and approved by the shareholders of the Company;

“**approved independent financial adviser**” means such independent financial adviser as approved by the Board;

“**Articles**” means the articles of association of the Company as amended from time to time;

“**associate(s)**” shall have the meaning ascribed to it in the Listing Rules;

“**Auditors**” means the auditors for the time being of the Company;

“**Board**” means the board of Directors from time to time or a duly authorised committee thereof;

“**Business Day**” means a day on which the Stock Exchange is open for the business of dealing in securities;

“**Cancelled Shares**” means those Shares which were the subject of options which had been granted and accepted under this Scheme or any of the other schemes but subsequently cancelled. For the avoidance of doubt, “**Cancelled Shares**” shall exclude “**Lapsed Shares**”;

“Company” means Ascentage Pharma Group International, a company incorporated in the Cayman Islands with limited liability on November 17, 2017;

“Companies Law” means the Companies Law (as revised) of the Cayman Islands, as amended, supplemented or otherwise modified from time to time;

“close associate(s)” shall have the meaning ascribed to it in the Listing Rules;

“connected person(s)” has the meaning ascribed to it in the Listing Rules;

“core connected person(s)” shall have the meaning ascribed to it in the Listing Rules;

“Director” means any director of the Company from time to time;

“Eligible Participant” means (a) any executive director of, manager of, or other employee holding an executive, managerial, supervisory or similar position in any member of the Group, any full-time or part-time employee, or a person for the time being seconded to work full-time or part-time for any member of the Group; (b) a director or proposed director (including an independent non-executive director) of any member of the Group ((a) and (b) collectively, the **“Employee Participant”**); and (c) a Service Provider;

“Exercise Date” means the date of the notice given by the Grantee in respect of the exercise of the Option in accordance with paragraph 7.1;

“Exercise Price” means the price per Share, determined by the Board, at which a Grantee may subscribe for Shares on the exercise of an Option in accordance with paragraph 6;

“Expiry Date” means, in respect of an Option, the date of the expiry of the Option as may be determined by the Board which shall not be later than the last day of the Option Period in respect of such Option;

“Global Offering” means offering of a total of 12,180,900 Shares (subject to reallocation and Over-allotment Option (as defined in the Prospectus)) for subscription, details of which are described in the section headed “Structure and Conditions of the Global Offering” in the Prospectus;

“Grantee” means any Eligible Participant who accepts an Offer in accordance with the rules of this Scheme;

“Group” means the Company and its Subsidiaries;

“HK\$” means Hong Kong dollars, the lawful currency of Hong Kong;

“Hong Kong” means the Hong Kong Special Administrative Region of the People’s Republic of China;

“Lapsed Shares” means those Shares which were the subject of options which had been granted and accepted under this Scheme or any of the other schemes but subsequently lapsed. For the avoidance of doubt, **“Lapsed Shares”** shall exclude **“Cancelled Shares”**;

“Listing Date” means the date on which the Shares commence listing on the Main Board of the Stock Exchange;

“Listing Rules” means the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended from time to time;

“Offer” means an offer of the grant of an Option or Options made in accordance with the Scheme;

“Offer Date” means in respect of an Option, the date on which such Option is offered in writing to an Eligible Participant which must be a Business Day;

“Option” means a right granted by the Company under the Scheme, which right permits (but does not obligate) a Grantee to subscribe for Shares in accordance with the terms of this Scheme;

“Option Period” means in respect of an Option, the period to be notified by the Board to each Grantee within which the Option may be exercisable provided that such period of time shall not exceed a period of ten years commencing on the Offer Date;

“other schemes” means other than this Scheme, all the schemes involving the grant by the Company of options or awards over Shares or other securities of the Company to, or for the benefit of, specified participants of such schemes or any arrangement involving the grant of options or awards to participants over Shares or other securities of the Company which, in the opinion of the Stock Exchange, is analogous to a share scheme as described in Chapter 17 of the Listing Rules;

“Personal Representative(s)” means a person or persons who, in accordance with the laws of succession applicable in respect of the death of such Grantee is or are entitled to exercise the Option accepted by such Grantee (to the extent not already exercised) in consequence of the death of such Grantee;

“Prospectus” means the prospectus of the Company in respect of the Global Offering;

“Remuneration Committee” means the remuneration committee of the Company established pursuant to the Listing Rules;

“Scheme” means the share option scheme, the rules of which are set out in this document in its present or any amended form;

“Scheme Mandate Limit” has the meaning ascribed to it in paragraph 9;

“**Scheme Limit**” has the meaning ascribed to it in paragraph 9;

“**Scheme Period**” means a period commencing on the Listing Date and ending on the tenth anniversary of the Listing Date (both dates inclusive);

“**Service Provider(s)**” means any person who provides services to the Group on a continuing or recurring basis in its ordinary and usual course of business which are in the interests of the long term growth of the Group, including: (a) supplier of goods or services to any member of the Group; and (b) a person or entity that provides design, research, development or other support or any advisory, consultancy, professional or other services to any member of the Group, provided that any placing agents or financial advisers providing advisory services to the Group for fundraising, mergers or acquisitions and professional services providers such as auditors or valuers who provide assurance or are required to perform their services with impartiality and objectivity should not be Service Providers for the purpose of the Scheme;

“**Service Provider Sublimit**” has the meaning ascribed to it in paragraph 9;

“**Shares**” means ordinary shares of US\$0.0001 each in the capital of the Company or, if there has been a capitalisation issue, rights issue, sub-division or consolidation of shares or reduction of capital in the share capital of the Company, shares forming part of the ordinary equity share capital of the Company of such other nominal amount as shall result from any such capitalisation issue, rights issue, sub-division or consolidation of shares or reduction of capital in the share capital of the Company;

“**Shareholders**” means the shareholders of the Company from time to time;

“**Special Resolution**” means a resolution passed at a meeting of the Grantees (being only those Grantees holding Options, all or any part of which is unexercised as at the time of the meeting at which the resolution is proposed) duly convened and held and carried by a majority consisting of not less than three-fourths of the votes cast upon a show of hands or if a poll is duly demanded, by a majority consisting of not less than three-fourths of the votes cast on a poll;

“**Stock Exchange**” means The Stock Exchange of Hong Kong Limited or (if applicable) such other stock exchange on which the issued share capital of the Company is primarily listed;

“**Subsidiary**” means an entity, including but not limited to such associate(s) as set forth in the accountants’ report of the Company from time to time, which is a subsidiary for the time being of the Company within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong) and “**Subsidiaries**” shall be construed accordingly;

“**substantial shareholder**” has the meaning ascribed to it in the Listing Rules;

“treasury Shares” has the meaning ascribed to it in the Listing Rules; and

“Vesting Period” means in respect of any particular Option, the period between the Offer Date and the day on which such Option vests and becomes exercisable, both days inclusive, and such period shall not be less than 12 months or such other period as the Listing Rules may prescribe or permit except otherwise permitted under this Scheme and/or the Listing Rules in respect of any particular Option granted to an Employee Participant.

1.2 In this Scheme, unless the context otherwise requires:

- (a) paragraph headings are inserted for convenience of reference only and shall not affect the interpretation of this Scheme;
- (b) references to paragraphs are to paragraphs of this Scheme;
- (c) the singular includes the plural and vice versa;
- (d) references to one gender shall include both genders and the neuter;
- (e) any reference to any statute or statutory provision shall include any statute or statutory provision which amends or replaces, or has amended or replaced it, and shall include any subordinate legislation made under the relevant statute; and
- (f) a reference to a “person” shall be construed so as to include any individual, firm, business, company, body corporate or unincorporated or other juridical person, government, federation, state or agency thereof or any joint venture, association, partnership or trust (whether or not having separate legal personality).

2. CONDITIONS

2.1 This Scheme shall take effect subject to and is conditional upon:

- (a) the passing of the necessary resolutions by the Shareholders to approve and adopt the rules of this Scheme and to authorise the Board to grant Options under this Scheme and to allot and issue Shares pursuant to exercise of any Options;
- (b) the Listing Committee of the Stock Exchange granting the listing of, and permission to deal in, the Shares falling to be issued pursuant to the exercise of Options under this Scheme;
- (c) the obligations of the Underwriters (as defined in the Prospectus) under the Underwriting Agreements (as defined in the Prospectus) becoming unconditional and not being terminated in accordance with its terms or otherwise; and
- (d) the listing of the Shares on the Stock Exchange.

Since the Amendment Date, the previous share option scheme adopted on September 28, 2019 shall be replaced in its entirety with this Scheme, provided that the options granted before the Amendment Date shall continue to be effective and exercisable in accordance with the terms and conditions thereunder.

3. PURPOSE, DURATION AND CONTROL OF SCHEME

3.1 The purpose of this Scheme is to enable the Company to grant Options to Eligible Participants as incentives or rewards for their contribution or potential contribution to the Group and to provide the Eligible Participants an opportunity to have a personal stake in the Company with the view to achieving the following objectives:

- (a) motivate the Eligible Participants to optimise their performance efficiency for the benefit of the Group;
- (b) attract and retain or otherwise maintain on-going business relationship with the Eligible Participants whose contributions are or will be beneficial to the long-term growth of the Group; and/or
- (c) for such purposes as the Board may approve from time to time.

3.2 The Board may, at its absolute discretion, invite the Eligible Participant to take up Options to subscribe for Shares. The basis of eligibility of any Eligible Participant to the grant of any Options shall be determined by the Board (or as the case may be, where required under the Listing Rules, the independent non-executive directors) from time to time on the basis of the Eligible Participant's contribution or potential contribution to the development and growth of the Group.

Eligible Participants under the Scheme include (i) any executive director of, manager of, or other employee holding an executive, managerial, supervisory or similar position in any member of the Group, any full-time or part-time employee, or a person for the time being seconded to work full-time or part-time for any member of the Group; (ii) a director or proposed director (including an independent non-executive director) of any member of the Group; ((i) and (ii) collectively, the **"Employee Participant"**); or (iii) a Service Provider. The basis of eligibility of any Eligible Participant to the grant of any Options shall be determined by the Board (or as the case may be, where required under the Listing Rules, the independent non-executive directors) from time to time on the basis of the Eligible Participant's contribution or potential contribution to the development and growth of the Group.

In determining eligibility of existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of the Group, the Board may take into account factors including, among others, (i) his/her skill, knowledge, experience, expertise and other relevant personal qualities, (ii) educational and professional qualifications, and knowledge in the industry, (iii) performance, length of employment with the Group, nature of duties and position within the Group, (iv) his/her adherence to the Group's culture and values, or (v) the contribution and potential contribution to the development of the Group.

Service Providers include any consultant who are experts in research and development, clinical trials and academia who provides consultancy services and/or other professional services to any member of the Group in connection with drug development and clinical trials in the ordinary and usual course of business of the Group which is in the interests of the long term growth of the Group, provided that any placing agents or financial advisers providing advisory services to the Group for fundraising, mergers or acquisitions and professional services providers such as auditors or valuers who provide assurance or are required to perform their services with impartiality and objectivity should not be Service Providers.

In determining the eligibility for such consultant to be a participant of the Scheme, the Board shall, in its absolute discretion, take into account, among others, (i) the skill, knowledge and expertise of the relevant consultant including his or her capability and technical know-how; (ii) his or her experience and network in the pharmaceutical industry and the academia; (iii) his or her research and development capability as well as his or her capability and know-how as to the conduct of clinical trials; (iv) the frequency of collaboration and length of business relationship with the Group; (v) the materiality and nature of the business relationship with the Group (such as whether they relate to the core business of the Group and whether such business dealings could be readily replaced by third parties and the relevant replacement costs); (vi) the background, reputation and track record of the relevant consultant; (vii) the potential and/or actual contribution to the business affairs of the Group, and in particular, whether such consultant could bring positive impacts to the Group's business, such as drug development and/or commercialization, an increase in revenue or profits or a reduction in costs attributable to or brought by services provided by such consultant; and (viii) other factors, including but not limited to the synergy between the relevant consultant and the Group.

- 3.3** Subject to paragraph 14 and fulfilment of the conditions in paragraph 2.1, this Scheme shall be valid and effective for the Scheme Period after which no further Options shall be offered but the provisions of this Scheme shall in all other respects remain in full force and effect to the extent necessary to give effect to the exercise of any Options granted prior thereto or otherwise as may be required in accordance with the provisions of this Scheme and Options granted prior thereto but not yet exercised shall continue to be valid and exercisable in accordance with this Scheme.
- 3.4** This Scheme shall be subject to the administration of the Board whose decision as to all matters arising in relation to this Scheme or its interpretation or effect (save as otherwise provided herein) shall be final and binding on all parties.

4. OPTIONS

- 4.1** The Board shall, subject to and in accordance with the provisions of this Scheme and the Listing Rules, be entitled to but shall not be bound, at any time on any Business Day during the Scheme Period, make an Offer to any Eligible Participant whom the Board may in its absolute discretion select and subject to such conditions (including, without limitation, any minimum period for which an Option must be held before it can be exercised and/or any performance targets which must be achieved before an Option can be exercised) as it may think fit, provided that the maximum number of Shares in respect of which Options may be granted under this Scheme to any Eligible Participant shall not result in the Shares issued and to be issued in respect of all options granted to such Eligible Participant (excluding any options lapsed in accordance with the terms of the respective schemes) in the 12-month period up to and including the Offer Date representing in aggregate over 1% of the total Shares in issue (excluding treasury shares).
- 4.2** If the Board determines to make an Offer to an Eligible Participant which exceed the limit set out in paragraph 4.1:
- (a) that grant shall be subject to (i) the issue of a circular by the Company to the Shareholders which shall comply with, and containing the information specified in, Rules 17.03D(2) and 17.06 of the Listing Rules and or such other requirements as prescribed under the Listing Rules from time to time; and (ii) the separate approval of the Shareholders, in the manner prescribed by the relevant provisions of the Listing Rules, in general meeting at which that Eligible Participant and his close associates (or his associates if the Eligible Participant is a connected person) shall abstain from voting;
 - (b) unless provided otherwise in the Listing Rules, the date of the Board meeting at which the Board resolves to grant the proposed Options to that Eligible Participant shall be taken as the Offer Date for the purpose of calculating the Exercise Price; and
 - (c) the number and terms (including the Exercise Price) of such Options are fixed before the general meeting of the Company at which the same are approved.
- 4.3** If the Board determines to make an Offer to an Eligible Participant in accordance with paragraph 4.1, the Board shall forward to the relevant Eligible Participant an offer document in such form as the Board may from time to time determine which states (or, alternatively, documents accompanying the offer document which state), among others:–
- (a) the Eligible Participant's name, address and occupation/position;
 - (b) the Offer Date;
 - (c) the Acceptance Date;

- (d) the date of commencement of the Option Period;
- (e) the number of Shares in respect of which the Option is offered;
- (f) the Exercise Price and the manner of payment of the Exercise Price for the Shares on and in consequence of the exercise of the Option;
- (g) the Expiry Date in relation to that Option;
- (h) the method of acceptance of the Option which shall, unless the Board otherwise determines, be as set out in paragraph 4.4; and
 - (i) such other terms, conditions, restrictions or limitations including (without prejudice to the generality of the foregoing) qualifying and/or continuing criteria, conditions, restrictions or limitations relating to the achievement of performance, operating or financial targets, the satisfactory performance or maintenance of certain conditions or obligations or the time or period before the Option can be exercised or any of the Shares shall be vested provided that such terms or conditions shall not be inconsistent with this Scheme. For the avoidance of doubt, subject to such terms and conditions as the Board may determine as aforesaid (including such terms and conditions in relation to their vesting, exercise or otherwise) there is no minimum period for which an Option must be held before it can be exercised and no performance target which need to be achieved by the Grantee before the Option can be exercised.

- 4.4** An Option shall be deemed to have been granted and accepted by the Grantee and to have taken effect when the duplicate offer document constituting acceptance of the Option duly signed by the Grantee, together with a remittance in favour of the Company of HK\$1.00 by way of consideration for the grant thereof is received by the Company on or before the relevant Acceptance Date. Such remittance shall in no circumstances be refundable and shall be deemed as part payment of the Exercise Price.
- 4.5** Any Offer may be accepted in respect of less than the number of Shares for which it is offered provided that it must be accepted in respect of a board lot for dealing in Shares on the Stock Exchange or an integral multiple thereof and such number is clearly stated in the duplicate offer document constituting acceptance of the Option in the manner as set out in paragraph 4.4. To the extent that the Offer is not accepted by the Acceptance Date, it shall be deemed to have been irrevocably declined.
- 4.6** The Options shall not be listed or dealt in on the Stock Exchange.
- 4.7** An Option and an Offer shall be personal to the Grantee and shall not be transferable or assignable and no Grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest (legal or beneficial) in favour of any third party over or in relation to any Option held by him or any Offer made to him or attempt to do so (save that the Grantee may nominate a nominee in whose name the Shares issued pursuant to this Scheme may be registered). Any breach of the foregoing shall entitle the Company to cancel any outstanding Options or any part thereof granted to such Grantee.

4.8 No offer of grant of Option shall be made after inside information has come to the knowledge of the Company until (and including) the trading day after such inside information has been published in accordance with the Listing Rules. In particular, no option may be granted during the period commencing 30 days immediately preceding the earlier of:

- (a) the date of the Board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and
- (b) the deadline for the Company to announce its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), and ending on the date of the results announcement. The period during which no Option may be granted will cover any period of delay in the publication of a results announcement.

No grant of Option to a Director shall be allowed during the period prohibited by the Model Code for Securities Transactions by Directors of Listed Issuers of the Listing Rules. If any Option is proposed to be granted to a Director, it shall not be granted, accepted or vested on any day on which the financial results of the Company are published and during the period of: (i) 60 days immediately preceding the publication date of the annual results or, if shorter, the period from the end of the relevant financial year up to the publication date of the results; and (ii) 30 days immediately preceding the publication date of the quarterly results (if any) and half-year results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results.

5. OPTIONS TO CONNECTED PERSONS

5.1 Subject to paragraphs 4.2, 5.2, 9.2 and 9.3, if the Board determines to make an Offer to a Director, chief executive or substantial shareholder of the Company or any of their respective associates, such grant shall be subject to the approval by the independent non-executive Directors (and in the event that the Board makes an Offer to an independent non-executive Director, the vote of such independent non-executive Director shall not be counted for the purposes of approving such grant). Each grant of Options to a Director, the chief executive or a senior management of the Company or any of their respective associates (as defined in the Listing Rules) under this Scheme or any other share schemes of the Company or any of its subsidiaries shall be subject to the approval of the Remuneration Committee.

- 5.2** If the Board determines to make an Offer to a substantial shareholder or an independent non-executive Director (or any of their respective associates) and that grant would result in the Shares issued and to be issued upon exercise of all options and awards already granted and to be granted (including options and awards exercised, cancelled and outstanding but excluding any options and awards lapsed in accordance with the terms of their respective schemes) to such person under this Scheme and the other schemes in the 12-month period up to and including the Offer Date, representing in aggregate over 0.1 per cent, or such other percentage as may be from time to time provided under the Listing Rules, of the Shares in issue (excluding treasury Shares) on the Offer Date; and, such grant shall be subject to, in addition to the approval of the independent non-executive Directors as referred to under paragraph 5.1, the issue of a circular by the Company to the Shareholders and the approval of the Shareholders in general meeting by way of a poll convened and held in accordance with the Articles at which the Grantee, his associates and all core connected persons of the Company shall abstain from voting in favour of the resolution concerning the grant of such Options at the general meeting, and/or such other requirements prescribed under the Listing Rules from time to time. Unless provided otherwise in the Listing Rules, the date of the Board meeting at which the Board proposes to grant the proposed Options to that Eligible Participant shall be taken as the Offer Date for the purpose of calculating the Exercise Price. If grant of Options involves Director(s), the relevant Director(s) should abstain from voting at the Board meeting or the Remuneration Committee meeting.
- 5.3** The circular to be issued by the Company to the Shareholders pursuant to paragraph 5.2 shall contain the following information:
- (a) the details of the number and terms (including the Exercise Price) of the Options to be granted to each Eligible Participant which must be fixed before the Shareholders' meeting and the Offer Date (which shall be the date of the Board meeting at which the Board proposes to grant the proposed Options to that Eligible Participant);
 - (b) the views of the independent non-executive Directors (excluding any independent non-executive Director who is the relevant Grantee) as to whether the terms of the grant are fair and reasonable and whether such grant is in the interests of the issuer and its shareholders as a whole, and their recommendation to the independent Shareholders as to voting;
 - (c) the information required under Rules 17.02(2)(c) of the Listing Rules; and
 - (d) the information required under Rule 2.17 of the Listing Rules.
- 5.4** The requirements in this paragraph 5 do not apply where the Eligible Participant is only a proposed director or chief executive of the Company.

6. EXERCISE PRICE

The Exercise Price in relation to each Option offered to an Eligible Participant shall, subject to the adjustments referred to in paragraph 10, be determined by the Board in its absolute discretion but in any event shall not be less than the highest of:

- (a) the closing price of the Shares as stated in the daily quotation sheets of the Stock Exchange on the Offer Date; and
- (b) the average of the closing price of the Shares as stated in the daily quotation sheets of the Stock Exchange for the five Business Days immediately preceding the Offer Date.

Without prejudice to the generality of the foregoing, the Board (or any duly authorized committee or person by the Board) may grant Options in respect of which the Exercise Price is fixed at different prices for different periods during the Option Period provided that the Exercise Price for Shares for each of the different period shall not be less than the Exercise Price determined in the manner set out in this paragraph 6.

7. EXERCISE OF OPTIONS

- 7.1** Subject to paragraph 7.3, an Option shall be exercised in whole or in part and, other than where it is exercised to the full extent outstanding, shall be exercised in integral multiples of such number of Shares as shall represent one board lot for dealing in Shares on the Stock Exchange for the time being, by the Grantee by giving notice in writing to the Company stating that the Option is thereby exercised and the number of Shares in respect of which it is exercised. Each such notice must be accompanied by a remittance for the full amount of the Exercise Price for the Shares in respect of which the notice is given. Within 30 days after receipt of the notice and the remittance of the Exercise Price and, where appropriate, receipt of the certificate by the Auditors or the approved independent financial adviser as the case may be pursuant to paragraph 10, the Company shall allot and issue the relevant number of Shares to the Grantee (or, as the case may be, his or her Personal Representative(s)) credited as fully paid and issue to the Grantee (or, as the case may be, his or her Personal Representative(s)) certificates in respect of the Shares so allotted.
- 7.2** The exercise of any Option may be subject to a vesting schedule to be determined by the Board in its absolute discretion which shall be specified in the offer letter. The exercise of any Option shall be subject to the Shareholders in general meeting approving any necessary increase in the authorised share capital of the Company.

Subject as hereinafter provided and to the extent as allowed by the relevant laws and regulations, as determinate otherwise by the Board, an Option may be exercised by a Grantee at any time or times during the Option Period provided that:–

- (a) in the event that the Employee Participant dies before exercising the Option in full, his/her legal personal representative(s) may exercise the Option up to the Employee Participant's entitlement (to the extent which has become exercisable and not already exercised) within the period of 12 months following his/her death provided that where any of the events set out in paragraph 7.3(d), (e) and (f) occurs prior to his/her death or within such 12-month period following his/her death, then his/her legal personal representative(s) may so exercise the Option within such of the various periods respectively set out in such paragraphs instead of the period referred to in this paragraph 7.3(a) and provided further that if within a period of 3 years prior to the Employee Participant's death, the Employee Participant had committed any of the acts as specified in paragraph 8.1(d) which would have entitled the Company to terminate his/her employment prior to his/her death, the Board may at any time forthwith terminate the Option of the Employee Participant (to the extent not already lapsed or exercised) by written notice to his/her legal personal representatives and the Option (to the extent not already exercised) shall lapse on the date of the relevant Board resolution;
- (b) in the event that the Grantee is an employee of the Group when an Offer is made to him/her and he/she subsequently ceases to be an employee of the Group for any reason other than (i) his/her death or (ii) the termination of his/her employment on one or more of the grounds specified in paragraph 8.1(d), the Option (to the extent not already lapsed or exercised) shall lapse on the expiry of 3 months after the date of cessation of such employment (which date will be the last actual working day on which the Grantee was physically at work with the Company or the relevant member of the Group whether salary is paid in lieu of notice or not);
- (c) in the event that the Grantee is an employee of the Group when an Offer is made to him/her and he/she subsequently ceases to be an employee by reason of a termination of his/her employment on one or more of the grounds specified in paragraph 8.1(d) and the Grantee has exercised the Option in whole or in part pursuant to paragraph 7.2, but Shares have not been allotted to him/her, the Grantee shall, unless the Board determines otherwise, be deemed not to have so exercised such Option and the Company shall return to the Grantee the amount of the Exercise Price for the Shares in respect of the purported exercise of such Option;
- (d) in the event of a general offer (whether by way of takeover offer or scheme of arrangement or otherwise in like manner) being made to all the Shareholders (or all such holders other than the offeror and/or any persons controlled by the offeror and/or any person acting in association or concert with the offeror) the Company shall use its best endeavours to procure that an appropriate offer is extended to all the Grantee (on comparable terms, mutatis mutandis, and assuming that they will become, by the exercise in full of the Options granted to them, as Shareholders). If such offer becoming or being declared unconditional, the Employee Participant (or, as the case may be, his/her legal personal representative(s)) shall, notwithstanding any terms on which his/her Options were granted, be entitled to exercise the Option in full (to the extent not already lapsed or exercised) at any time within 1 month after the date on which the offer becomes or is declared unconditional;

- (e) in the event of a compromise or arrangement between the Company and the Shareholders or its creditors being proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies pursuant to the Companies Law, the Company shall give notice thereof to all the Grantees on the same day as it gives notice of the meeting to the Shareholders or its creditors to consider such a compromise or arrangement and the Options (to the extent not already lapsed or exercised) granted to an Employee Participant shall become exercisable in whole or in part not later than 2 Business Days prior to the date of the general meeting directed to be convened by the court for the purposes of considering such compromise or arrangement (the “**Suspension Date**”), by giving notice in writing to the Company in accordance with paragraph 7.2, accompanied by a remittance for the full amount of the aggregate Exercise Price for the Shares in respect of which the notice is given whereupon the Company shall as soon as practicable and, in any event, no later than 3:00 p.m. on the Business Day immediately prior to the date of the proposed general meeting, allot and issue the relevant Shares to the Employee Participant credited as fully paid. With effect from the Suspension Date, the rights of all Grantees to exercise their respective Options shall forthwith be suspended. Upon such compromise or arrangement becoming effective, all Options shall, to the extent that they have not been exercised, lapse and determine. The Board shall endeavour to procure that the Shares issued as a result of the exercise of Options under this paragraph 7.3(e) shall for the purposes of such compromise or arrangement form part of the issued share capital of the Company on the effective date thereof and that such Shares shall in all respects be subject to such compromise or arrangement. If for any reason such compromise or arrangement is not approved by the court (whether upon the terms presented to the court or upon any other terms as may be approved by such court), the rights of Employee Participants to exercise their respective Options shall with effect from the date of the making of the order by the court be restored in full but only up to the extent not already exercised and shall thereupon become exercisable (but subject to the other terms of this Scheme) as if such compromise or arrangement had not been proposed by the Company and no claim shall lie against the Company or any of its officers for any loss or damage sustained by any Employee Participant as a result of such proposal, unless any such loss or damage shall have been caused by the act, neglect, fraud or wilful default on the part of the Company or any of its officers;
- (f) in the event a notice is given by the Company to its members to convene a general meeting for the purposes of considering, and if thought fit, approving a resolution to voluntarily wind-up the Company, the Company shall on the same date as or soon after it despatches such notice to each member of the Company give notice thereof to all Grantees and thereupon, each Employee Participant shall be entitled to exercise all or any of his Options (to the extent not already lapsed or exercised) at any time not later than 2 Business Days prior to the proposed general meeting of the Company by giving notice in writing to the Company in accordance with paragraph 7.1, accompanied by a remittance for the full amount of the aggregate Exercise Price of the Shares in respect of which the notice is given whereupon the Company shall as soon as possible and, in any event, no later than the Business Day immediately prior to the date of the proposed general meeting referred to above, allot the relevant Shares to the Employee Participant credited as fully paid.

- 7.4 The Shares to be allotted upon the exercise of an Option will be subject to all the provisions of the memorandum of association and the Articles and the laws of the Cayman Islands from time to time and shall rank *pari passu* in all respects with the then existing fully paid Shares in issue on the allotment date or, if that date falls on a day when the register of members of the Company is closed, the first date of the re-opening of the register of members, and accordingly will entitle the holders to participate in all dividends or other distributions paid or made on or after the allotment date or, if that date falls on a day when the register of members of the Company is closed, the first day of the re-opening of the register of members, other than any dividend or other distribution previously declared or recommended or resolved to be paid or made if the record date therefore shall be before the allotment date.
- 7.5 A Share issued upon the exercise of an Option shall not carry rights until the registration of the Grantee (or any other person) as the holder thereof.
- 7.6 There is no general requirement for any performance target that has to be achieved before any Option can become vested and exercisable except as otherwise imposed by the Board (or any duly authorized committee or person by the Board) and stated in the offer of grant of an Option.
- 7.7 The Options may be vested over such period as determined by the Board (or any duly authorized committee or person by the Board) in its absolute discretion. The periods over which the Options will vest shall not be less than 12 months or such other minimum vesting periods prescribed from time to time by any laws, regulations or rules to which this Scheme may be subject, including the Listing Rules or regulations of any stock exchange on which the Shares may be listed and quoted. Furthermore the Shares to be issued and allotted to a Grantee pursuant to the exercise of any Option under this Scheme may or may not, at the discretion of the Board (or any duly authorized committee or person by the Board), be subject to any retention period. An Option granted to an Employee Participant may be subject to a shorter Vesting Period under specific circumstances which include but not limited to those as set out below:
- (a) grants of “make-whole” Options to an Employee Participant (who is a new joiner) to replace the options he forfeited when leaving his previous employer(s). In such case, the Vesting Period may be shorter to reflect the remaining vesting period in respect of the forfeited options;
 - (b) grants of “make-whole” Options to an Employee Participant who is an existing key personnel of a newly acquired Subsidiary of the Company to replace the options he forfeited upon the acquisition of the Subsidiary by the Company. In such case, the Vesting Period may be shorter to reflect the remaining vesting period in respect of the forfeited options;

- (c) grants to an Employee Participant whose employment is terminated due to retirement, death, disability, or reasons other than resignation or Cause. In such circumstance(s), the vesting of an Option may accelerate;
- (d) grants of Options with performance-based vesting condition(s), in lieu of time-based vesting criteria;
- (e) grants that are made in batches during a year for administrative and compliance reasons, which may include Options that should have been granted earlier but had to wait for a subsequent batch. In such cases, the vesting periods may be shorter to reflect the time from which an Option would have been granted;
- (f) grants of Options with a mixed or accelerated vesting schedule such as where such Options may vest evenly over a period of 12 months;
- (g) grants of Options with a total Vesting Period and holding period of more than 12 months; or
- (h) grants of Options as the year-end bonus of such Employee Participant.¹

8. CLAWBACK MECHANISM – LAPSE OF OPTION

8.1 The Company can clawback an Option by treating it as lapsed automatically and not be exercisable (to the extent not already exercised) on the earliest of –

- (a) the expiry of the Option Period;
- (b) the expiry of any of the periods referred to in paragraphs 7.3(a), (b), (d) or (f);
- (c) subject to paragraph 7.3 (f), the date of the commencement of the winding-up of the Company;
- (d) in the event that the Grantee is an employee of the Group when an Offer is made to him/her and he/she subsequently ceases to be an employee of the Group on any one or more of the grounds that he/she has been guilty of serious misconduct, or has

¹ The Directors and the Remuneration Committee are of the view that the vesting period (including the circumstances in which a shorter vesting period may apply), as detailed above, enables the Company to offer competitive remuneration and reward packages to Employee Participants, on an ad hoc basis, in such circumstances that would be justified and reasonable, which is also consistent with the Listing Rules and the former practice of the Company and peer companies in the Group's industry. In particular, Options granted as year-end bonuses to Employee Participants may have a shorter vesting period as, despite year-end bonuses being a reward for satisfactory past performance in nature, providing year-end bonuses in the form of Options as opposed to cash would link the value of the year-end bonuses to the future performance of the Group as well, thereby encouraging and incentivizing Employee Participants to continue committing and contributing to the development and expansion of the Group and its business. Accordingly, the above vesting period is considered appropriate and aligns with the purpose of the Scheme. committed an act of bankruptcy or has become insolvent or has made any arrangement or composition with his/her creditors generally, or has been convicted of any criminal offence involving his/her integrity or honesty or (if so determined by the Board) on any other ground on which an employer would be entitled to terminate his/her employment at common law or pursuant to any applicable laws or under the Grantee's service contract with the Group, the date of cessation of his/her employment with the Group. A resolution of the Board or the board of directors of the relevant member of the Group to the effect that employment of a Grantee has or has not been terminated on one or more of the grounds specified in this paragraph 8.1(d) shall be conclusive and binding on the Grantee;

- (e) the date on which the Board exercises the Company's right to cancel, revoke or terminate the Option on the ground that the Grantee commits a breach of paragraph 7.1 in respect of that or any other Option;
- (f) where the Grantee is only a substantial shareholder of any member of the Group, the date on which the Grantee ceases to be a substantial shareholder of such member of the Group;
- (g) subject to the compromise or arrangement as referred to in paragraph 7.3(e) becoming effective, the date on which such compromise or arrangement becomes effective; or
- (h) unless otherwise determined by the Board (or any duly authorized committee or person by the Board), the performance target in relation to the exercise of any Option cannot be achieved.

8.2 No compensation shall be payable upon the lapse of any Option, provided that the Board shall be entitled in its discretion to pay such compensation to the Grantee in such manner as it may consider appropriate in any particular case.

9. MAXIMUM NUMBER OF SHARES AVAILABLE FOR SUBSCRIPTION

Unless further approval has been obtained pursuant to paragraphs 9.4 and subject to paragraphs 9.2, 9.5 and 9.6, the maximum number of Shares in respect of which Options under the Scheme may be granted and yet to be exercised (including options that have been cancelled but excluding those lapsed in accordance with the terms of the respective share schemes) is 14,907,462 Shares, representing 4.2783% of the total Shares in issue (excluding treasury Shares) as at the Amendment Date (the "**Scheme Limit**").

9.1 The Shares which may be issued in respect of all options and awards to be granted under this Scheme and any other share schemes of the Company (including options or awards that have been cancelled but excluding those lapsed in accordance with the terms of the respective share schemes) shall not exceed 29,113,683 Shares (representing 10% of the number of Shares in issue (excluding treasury Shares) on the Amendment Date) (the "**Scheme Mandate Limit**").

- 9.2** Subject to the Scheme Limit and the Scheme Mandate Limit, the maximum number of Shares in respect of which Options under the Scheme may be granted to the Service Providers and yet to be exercised (including options or awards have been cancelled but excluding those lapsed in accordance with the terms of the respective share schemes) is 3,483,089 Shares, representing one per cent (1%) of the Shares in issue (excluding treasury Shares) as at the Amendment Date (the “**Service Provider Sublimit**”).
- 9.3** Subject to paragraphs 9.1 and 9.2, the Company may seek approval of the Shareholders in general meeting for refreshing the Scheme Limit, the Scheme Mandate Limit and/or the Service Provider Sublimit every three years after the Amendment Date or the shareholder approval date of the last refreshment, as the case may be. However, the Scheme Mandate Limit as refreshed shall not exceed 10% of the total number of Shares in issue (excluding treasury Shares) as at the date of approval of the refreshed scheme mandate. Any refreshment within any three year period must be approved by Shareholders subject to the following or other terms under the applicable listing rules and laws and regulations: (i) any controlling shareholders (as defined in the Listing Rules) and their associates (or if there is no controlling shareholders, Directors (excluding the independent non-executive Directors) and the chief executive of the Company and their respective associates) must abstain from voting in favor of the relevant resolutions at the general meeting; and (ii) the Company must comply with the requirement of independent shareholder approval. A circular containing the information required under the Listing Rules shall be sent to the Shareholders in connection with the meeting at which their approval will be sought.
- Thereafter, as at the Offer Date of any proposed grant of Options, the maximum number of Shares in respect of which Options may be granted is the Scheme Limit as refreshed less the aggregate of the following Shares as at that Offer Date:
- (a) the number of Shares which would be issued on the exercise in full of the Options and options under the other schemes granted on or after the date of approval of the refreshed scheme mandate but not cancelled, lapsed or exercised;
 - (b) the number of Shares which have been issued and allotted pursuant to the exercise of any Options or options under the other schemes granted on or after the
 - (c) the number of Cancelled Shares, the subject of Options or options under the other schemes granted on or after the date of approval of the refreshed scheme mandate.
- 9.4** The Company may seek separate approval by the Shareholders in general meeting for granting Options beyond the Scheme Limit PROVIDED THAT:
- (a) the Grantee(s) of such Option(s) must be specifically identified by the Company before such approval is sought;

- (b) a circular containing a generic description of the specified Grantees who may be granted such Options, the number and terms of the Options to be granted, the purpose of granting such Options to the Grantees with an explanation as to how the terms of Options serve such purpose and other information required by the Listing Rules shall be sent to the Shareholders;
- (c) the number and terms of such Options are fixed before the general meeting of the Company at which the same are approved; and
- (d) unless provided otherwise in the Listing Rules, the date of the Board meeting at which the Board resolves to grant the proposed Options to that Eligible Participant shall be taken as the Offer Date for the purpose of calculating the Exercise Price.

9.5 The Scheme Limit, Service Provider Sublimit and Scheme Mandate Limit referred to in paragraphs 9.1, 9.2 and 9.3 (or as refreshed in accordance with paragraphs 9.4, as the case may be) shall be adjusted, in such manner as the Auditors or the approved independent financial adviser shall certify to be appropriate, fair and reasonable in the event of any alteration in the capital structure of the Company in accordance with paragraph 10 whether by way of capitalisation issue, rights issue, sub-division or consolidation of shares or reduction of share capital of the Company.

10. CAPITAL RESTRUCTURING

10.1 In the event of any capitalisation issue, rights issue, sub-division or consolidation of shares or reduction of capital of the Company in accordance with applicable laws and regulatory requirements, such corresponding alterations (if any) shall be made (except on an issue of securities of the Company as consideration in a transaction which shall not be regarded as a circumstance requiring alteration or adjustment) in:

- (a) the number of Shares subject to any outstanding Options; and
- (b) the Exercise Price,

as the Auditors shall certify in writing or the approved independent financial adviser shall confirm in writing (as the case may be) to the Board to be in their opinion fair and reasonable and in compliance with the relevant provisions of the Listing Rules (or any guideline or supplementary guidance as may be issued by the Stock Exchange from time to time) (no such certification or confirmation is required in case of adjustment made on a capitalisation issue), provided that any such alteration shall give a Grantee as near as possible the same proportion of the issued share capital of the Company (rounded to the nearest whole share) as (but in any event shall not be greater than) that to which he/she/it was previously entitled and any such adjustments shall be made on the basis that the aggregate Exercise Price payable by a Grantee on the full exercise of any Option shall remain as nearly as possible the same (but shall not be greater than, except upon any consolidation of the Shares pursuant to this paragraph 10) it was before such event, but no adjustment shall be made to the effect of which would be to enable a Share to be issued at less than its nominal value.

The capacity of the Auditors or the approved independent financial adviser (as the case may be) in this paragraph 10 is that of experts and not of arbitrators and their certification or confirmation shall, in the absence of manifest error, be final, conclusive and binding on the Company and the Grantees. The costs of the Auditors or the approved independent financial adviser (as the case may be) shall be borne by the Company.

Subject to the above principles and certification procedures, and any further or updated guidance or interpretation of the Listing Rules from time to time, the default method of adjustment shall be made in accordance with FAQ13 – No. 1-20 and its appendix (Supplementary Guidance on Main Board Listing Rule 17.03(13) and the Note to the Rule) (the “**Supplementary Guidance**”) published by the Stock Exchange, which for the ease of reference, has been set out below:

- (1) In the case of a capitalization issue, bonus issue, rights issue or open offer of shares, the Company would calculate the adjusted number of Options and adjusted exercise price by applying the formula prescribed (and as updated from time to time) by the Stock Exchange in section I of the Supplementary Guidance, set out below:

New number of Options = Existing Options x F

New Exercise Price = Existing Exercise Price x 1/F

Where

$$F = \frac{\text{CUM}}{\text{TEEP}}$$

CUM = Closing price as shown in the Daily Quotation Sheet of the Exchange on the last day of trading before going Ex-Entitlement

$$\text{TEEP (Theoretical Ex Entitlement Price)} = \frac{\text{CUM} + \text{M} \times \text{R}}{1 + \text{M}}$$

M = Entitlement per existing Share

R = Subscription Price

- (2) In the case of a sub-division of shares or reduction of the share capital, the Company would calculate the adjusted number of Options and adjusted exercise price by applying the formula prescribed (as updated from time to time) by the Stock Exchange in section II of the Supplementary Guidance set out below:

New number of Options = Existing Options x F

New Exercise Price = Existing Exercise Price x 1/F

Where F = Subdivision or Consolidation Factor.

Upon any adjustment pursuant to paragraph 10.1, the Company shall notify the Grantees in writing the adjustments that have been made. If there has been any alteration in the capital structure of the Company, and if the Company has not yet informed the Grantees of any necessary adjustments to be made to their Options in accordance with the certificate of the Auditors or the confirmation of the approved independent financial adviser (as the case may be), the Company shall, upon receipt of a notice from a Grantee in accordance with paragraph 7.1, inform the Grantee of such alteration and shall either inform the Grantee of the adjustment to be made in accordance with the aforesaid certificate or confirmation obtained by the Company for such purpose or, if no such certificate or confirmation has yet been obtained, inform the Grantee of such fact and instruct the Auditors or the approved independent financial adviser as soon as practicable thereafter to issue a certificate or provide a written confirmation in that regard in accordance with paragraph 10.1.

11. SUFFICIENT SHARE CAPITAL

Subject to paragraph 7.2, the Board shall at all times set aside for the purposes of this Scheme, out of the authorised but unissued share capital of the Company, such number of Shares as the Board may from time to time determine to be sufficient to meet subsisting requirements for the exercise of outstanding Options.

12. DISPUTES

Any dispute arising in connection with this Scheme (whether as to the number of Shares subject to an Option, the amount of the Exercise Price or otherwise) shall be referred to the Auditors or the approved independent financial advisor to the Company who shall act as experts and not as arbitrators and whose decision shall, in the absence of manifest error, be final, conclusive and binding on all persons who may be affected thereby. The costs of the Auditors or the approved independent financial advisor to the Company shall be borne equally by the Company and the relevant Grantee.

13. ALTERATION OF THIS SCHEME

- 13.1** Subject to paragraph 13.2 below, and the compliance with the Listing Rules, save for any alternations to this Scheme which are of a material nature of any alterations to the provisions relating to the matters set out in Rule 17.03 of the Listing Rule to the advantage of the Eligible Participants must be approved by the Shareholders in general meeting, the Board may amend any of the provisions of the Scheme (including without limitation to amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of this Scheme, which are not found in Chapter 17 of the Listing Rules) at any time.
- 13.2** Subject to compliance with the Listing Rules, any change to the terms of the Options granted to a Grantee must be approved by the Board, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, as the case may be, if the initial grant of the Options was approved by the Board, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, correspondingly. This requirement does not apply to the alterations take effect automatically under the existing terms of this Scheme. The amended terms of this Scheme must still comply with the applicable provisions of the Listing Rules.
- 13.3** Notwithstanding anything to the contrary contained in paragraphs 13.1, 13.2, 13.3 and 13.4, the Board may at any time alter or modify the Scheme in any way to the extent necessary to cause the Scheme to comply with any statutory provisions or the regulations of any regulatory or other relevant authority. Any amendment to any terms of the Scheme or the options granted shall comply with the relevant requirements of Chapter 17 of the Listing Rules.

14. TERMINATION

- 14.1** The Company by resolution in general meeting or the Board may at any time resolve to terminate the operation of this Scheme and in such event no further Offers shall be made but the provisions of this Scheme shall remain in force to the extent necessary to give effect to the exercise of any Option granted prior to the termination or otherwise as may be required in accordance with the provisions of this Scheme and Options granted prior to such termination shall continue to be valid and exercisable in accordance with this Scheme.

15. CLAWBACK MECHANISM – CANCELLATION OF OPTIONS

- 15.1** Any cancellation of Options granted but not exercised may be effected on such terms as may be agreed with the relevant Grantee, as the Board may in its absolute discretion sees fit and in a manner that complies with all applicable legal requirements for such cancellation. Where the Company cancels Options and issues new ones to the same Grantee, the issue of such new Options may only be made under this Scheme with available unissued Options (excluding the cancelled Options) and in compliance with the terms of this Scheme, in particular within the limit approved by the Shareholders and, subject to the maximum number of Shares available for subscription referred to in paragraphs 9.1, 9.2, 9.3 and 9.4.

- 15.2** The Board shall be entitled for the following causes to clawback any Option by cancelling the same in whole or in part by giving notice in writing to the Grantee stating that such Option is thereby cancelled with effect from the date specified in such notice (the “**Cancellation Date**”):-
- (a) the Grantee commits or permits or attempts to commit or permit a breach of the restriction on transferability of Option or any terms or conditions attached to the grant of the Option;
 - (b) the Grantee makes a written request to the Board for the Option to be cancelled; or
 - (c) if the Grantee has, in the opinion of the Board, conducted himself in any manner whatsoever to the detriment of or prejudicial to the interests of the Company or its Subsidiary.
- 15.3** The Option shall be deemed to have been cancelled with effect from the Cancellation Date in respect of any part of the Option which has not been exercised as of the Cancellation Date. No compensation shall be payable upon any such cancellation, provided that the Board shall be entitled in its discretion to pay such compensation to the Grantee in such manner as it may consider appropriate in any particular case.
- 15.4** Cancelled Options will be regarded as utilized for the purpose of calculating the Scheme Mandate Limit and the Service Provider Sublimit. Where the Company cancels Options and issues new ones to the same Grantee, the issue of such new Options may only be made under a scheme with available unissued Options within the limit as mentioned in paragraph 9.
- 16. DISCLOSURE IN ANNUAL AND INTERIM REPORTS**
- The Board shall procure that details of this Scheme and other schemes of the Group including such details as required under the Listing Rules are disclosed in the annual reports and interim reports of the Company in compliance with the Listing Rules in force from time to time.
- 17. GENERAL**
- 17.1** The Company shall bear the costs of establishing and administering this Scheme (including the costs of the Auditors or the approved independent financial advisor, as the case may be, in relation to the preparation of any certificate or the provision of any other services in relation to this Scheme).

- 17.2** A Grantee shall be entitled to inspect copies of all notices and other documents sent by the Company to Shareholders at the same time or within a reasonable time of any such notices or documents being sent, which shall be made available to him, during normal office hours at the Company's principal place of business in Hong Kong.
- 17.3** Any notices, documents or other communication between the Company and a Grantee shall be in writing and may be given by sending the same by prepaid post or by personal delivery to, in the case of the Company, its principal place of business in Hong Kong and, in the case of the Grantee, his address in Hong Kong as notified to the Company from time to time.
- 17.4** Any notice or other communication served:
- (a) by the Company shall be deemed to have been served 48 hours after the same was put in the post or if delivered by hand, when delivered; and
 - (b) by the Grantee shall not be deemed to have been received until the same shall have been received by the Company.
- 17.5** All allotments and issues of Shares pursuant to this Scheme shall be subject to any necessary consents under the relevant laws, enactments or regulations for the time being to which the Company is subject. A Grantee shall be responsible for obtaining any governmental or other official consent that may be required by any country or jurisdiction for, or in connection with the grant or exercise of an Option. The Company shall not be responsible for any failure by a Grantee to obtain any such consent or for any tax or other liability to which a Grantee may become subject as a result of his participation in this Scheme.
- 17.6** This Scheme shall not confer on any person any legal or equitable rights (other than those constituting the Options themselves) against the Company directly or indirectly or give rise to any cause of action at law or in equity against the Company.
- 17.7** This Scheme shall not form part of any contract of employment between the Group and any Eligible Participant who is an employee of the Group and the rights and obligations of any Eligible Participant under the terms of his office or employment shall not be affected by his participation in it and this Scheme shall afford such an Eligible Participant no additional rights to compensation or damages in consequence of the termination of such office or employment for any reason.
- 17.8** The Company shall maintain all necessary books of account and records relating to the Scheme.
- 17.9** This Scheme shall in all respects be administered by the Board which (a) shall administer the Scheme in accordance with the provisions hereof and all applicable requirements of the Listing Rules and (b) may make such rules not being inconsistent with the terms and conditions hereof and the Listing Rules for the conduct of the Scheme and the determination and terms of each entitlement under an Option as the Board thinks fit.
- 17.10** A Grantee who is a member of the Board may, subject to and in accordance with the Articles, notwithstanding his interest, vote on any Board resolution concerning the Scheme (other than in respect of his own participation therein) and may retain any benefit under the Scheme. The Options do not carry any right to vote in the general meetings of the Company, or any right to dividend, or transfer rights or any other rights whether or not arising on the liquidation of the Company.

18. GOVERNING LAW

This Scheme and all Options granted hereunder are governed by and shall be construed in accordance with the laws of Hong Kong.

RULES
OF
ASCENTAGE PHARMA GROUP
INTERNATIONAL
RESTRICTED SHARE UNIT SCHEME 2021
Adopted on February 2, 2021 and amended on May 19, 2025

RULES
OF
ASCENTAGE PHARMA GROUP INTERNATIONAL
RESTRICTED SHARE UNIT SCHEME

1. Purpose

The purpose of this Scheme is to incentivize the existing and incoming directors, senior management and employees for their contribution to our Group, to attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of the Group by providing them with the opportunity to own equity interests in the Company.

2. Definitions and interpretation

2.1 Defined Terms

In these Rules, except where the context otherwise requires, the following expressions shall have the following meanings:

“Adoption Date” means the date of the adoption of this Scheme by the Board of the Company on February 2, 2021, and not being the Amendment Date for the avoidance of doubt;

“Amendment Date” means May 19, 2025 (the date on which amendment to this Scheme is duly conditionally approved and adopted by the Company);

“Articles” means the articles of association of the Company (as amended from time to time);

“Award(s)” means award(s) of RSUs granted to a Selected Person pursuant to this Scheme;

“Award Period” means the period during which the Award can be vested, which will be notified by the Board to each Selected Person at the time of making an offer of any Award, which shall not be longer than ten (10) years from the Grant Date of the Award;

“Auditors” means the auditors of the Company, as appointed from time to time;

“Board” means the board of directors of the Company or a duly authorized committee thereof;

“**Board Lot**” means 100 Shares;

“**Business Day**” a day (other than a Saturday or Sunday or days on which a tropical cyclone warning number 8 or above or a “black” rain warning signal is hoisted in Hong Kong at any time between 9 am and 5 pm) on which the Stock Exchange is open for trading and clearing banks in Hong Kong and the PRC are open for transactions of normal banking business;

“**Company**” means Ascentage Pharma Group International, a company incorporated under the laws of the Cayman Islands with limited liability on November 17, 2017;

“**Directors**” means the directors of the Company and “Director” shall be construed accordingly;

“**Eligible Persons**” means persons eligible to receive RSUs under this Scheme, who are existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of the Group or a Service Provider;

“**Grant Date**” means the date on which RSUs, are granted under this Scheme pursuant to a Grant Letter, as described in Rule 5.4;

“**Grant Letter**” means the letter pursuant to which RSUs are granted to a Selected Person, as described in Rule 5.3;

“**Group**” means the Company, its subsidiaries and companies whose financial results have been consolidated and accounted as the subsidiaries of the Company by virtue of the contractual arrangements; a “**member of the Group**” shall mean any of the aforesaid companies;

“**Hong Kong**” means the Hong Kong Special Administrative Region of the People’s Republic of China;

“**Listing Date**” means October 28, 2019, on which the Shares were listed and from which dealings therein were permitted to take place on the Stock Exchange;

“**Listing Rules**” means the Rules Governing the Listing of Securities on the Stock Exchange, as amended from time to time;

“**Participant(s)**” means a Selected Person who accepts the offer of the grant of RSUs in accordance with the terms of this Scheme;

“**PRC**” means the People’s Republic of China, and for the purpose of this Scheme, exclude Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan;

“Remuneration Committee” the remuneration committee of the Company established pursuant to the Listing Rules;

“RSUs” means restricted share units, each restricted share unit represents one underlying Share, and represent a conditional right granted to any Selected Person under this Scheme to obtain the corresponding economic value of the underlying Shares, less any tax, stamp duty and other charges applicable, as determined by the Board in its absolute discretion;

“Rules” means the rules of this Scheme as amended from time to time;

“Scheme” means the restricted share unit scheme constituted and governed by the rules in this document, as amended from time to time;

“Scheme Period” means the period of ten (10) years commencing from the Adoption Date, or until this Scheme is terminated pursuant to Rule 17, whichever is earlier;

“Selected Person(s)” means Eligible Persons selected by the Board to be granted RSUs under this Scheme at its discretion;

“Service Provider(s)” means any person who provides services to the Group on a continuing or recurring basis in its ordinary and usual course of business which are in the interests of the long term growth of the Group, including: (a) supplier of goods or services to any member of the Group; and (b) a person or entity that provides design, research, development or other support or any advisory, consultancy, professional or other services to any member of the Group, provided that any placing agents or financial advisers providing advisory services to the Group for fundraising, mergers or acquisitions and professional services providers such as auditors or valuers who provide assurance or are required to perform their services with impartiality and objectivity should not be Service Providers for the purpose of the Scheme;

“Service Provider Sublimit” has the meaning scribed to it in Rule 13;

“SFO” means the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), as amended from time to time;

“Shareholders” means the shareholders of the Company;

“Shares” means Ordinary Shares of US\$0.0001 each in the issued share capital of the Company (or of such other nominal amount as shall result from other sub-division or a consolidation of the share capital of the Company from time to time);

“Stock Exchange” means The Stock Exchange of Hong Kong Limited;

“Trustee” means the trustee(s) to be appointed by the Board to hold Shares for the purpose of this Scheme;

“Vesting Date” means any Share held by the Trustee on behalf of a Participant pursuant to the provisions of the Rules vests in such Participant in accordance with the vesting schedule (if any) as set out in the grant letter; and

“Vesting Notice” means a notice to be sent by the Company to each of the relevant Participants after the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, as described in Rule 6.2.

2.2 Headings are inserted for reference only and shall be ignored in the interpretation of these Rules. Unless the context otherwise requires, references herein to Rules are to provisions of these Rules, references to persons includes corporations and vice versa, singular includes the plural and vice versa and references to a gender shall include all genders.

2.3 References to any document in these Rules are to that document as amended, consolidated, supplemented, novated or replaced from time to time.

2.4 References to statutes, statutory provisions or the Listing Rules shall be construed as references to those statutes, provisions or rules as respectively amended or re-enacted or as their application is modified from time to time by other provisions (whether before or after the date of this Scheme).

3. Duration and administration

3.1 *Term of this Scheme*

Subject to Rule 17, this Scheme shall be valid and effective for a period of ten (10) years, commencing on the Adoption Date, after which period no further Awards shall be granted or accepted, but the provisions of this Scheme shall remain in full force and effect in order to give effect to the vesting of Awards granted and accepted prior to the expiration of the Scheme Period. Awards granted hereunder shall continue to be exercisable subject to the terms of this Scheme and in accordance with their terms of grant after the end of the ten (10) year period until the end of the Award Period.

3.2 *Administration of Scheme*

The Board has the power to administer this Scheme, including the power to construe and interpret these Rules and the terms of the RSUs granted under it. The Board may delegate the authority to administer this Scheme to a committee of the Board. The Board may also appoint one or more independent third-party contractors to assist in the administration of this Scheme and delegate such powers and/or functions relating to the administration of this Scheme as the Board thinks fit (the “**RSU Administrator**”). The Board’s determinations under this Scheme need not be uniform and may be made by it selectively with respect to persons who are granted, or are eligible to be granted, RSUs under it. If a director is a Participant he may, notwithstanding his/her own interest and subject to the Articles, vote on any Board resolution concerning this Scheme (other than in respect of his/her own participation in it), and may retain RSUs under it. Each Participant waives any right to contest, amongst other things, the value and number of RSUs or Shares or equivalent value of cash underlying the RSUs or Shares and the Board’s administration of this Scheme.

3.3 Interpretation of Scheme

The decision of the Board as to all matters relating to this Scheme or its interpretation or effect shall be final and binding. In particular, the Board shall finally determine whether a person is eligible to participate in this Scheme.

3.4 Trustee

The Company may appoint trustee to assist with the administration and vesting of RSUs granted pursuant to this Scheme. The Company may (i) allot and issue Shares under its available Scheme Mandate Limit to the Trustee to be held by the Trustee and which will be used to satisfy the RSUs upon vesting and/or (ii) direct and procure the Trustee to receive existing Shares from any shareholder of the Company or purchase existing Shares on-market to satisfy the RSUs upon vesting. The Company shall procure that sufficient funds are provided to the Trustee by whatever means as the Board may in its absolute discretion determine to enable the Trustee to satisfy its obligations in connection with the administration of this Scheme. All Shares underlying the RSUs granted and to be granted under the Scheme will be transferred, allotted or issued to the Trustee.

The Trustee holding unvested Shares of the Scheme, whether directly or indirectly, shall abstain from voting on matters that require shareholders' approval under the Listing Rules, unless otherwise required by law to vote in accordance with the beneficial owner's direction and such a direction is given.

4. Assignment of RSUs

The RSUs granted pursuant to this Scheme are personal to each Participant and are not assignable. Participants are prohibited from selling, transferring, assigning, charging, mortgaging, encumbering, hedging or creating any interest in favor of any other person over or in relation to any property held by the Trustee on trust for the Participants, the RSUs, or any interest or benefits therein.

5. Grant of RSUs

5.1 Basis of eligibility for RSUs

Subject to Rules 5.2 and 5.6, the Board may select any Eligible Person for participation in this Scheme as a Selected Person. Unless so selected, no Eligible Person shall be entitled to participate in this Scheme. The basis of eligibility of any Selected Person for the grant of RSUs shall be determined by the Board from time to time on the basis of their contribution to the development and growth of the Group or such other factors as the Board may deem appropriate.

Eligible participants under the Scheme include (i) existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of the Group, or (ii) a Service Provider. The basis of eligibility of any Selected Person for the grant of RSUs shall be determined by the Board from time to time on the basis of their contribution to the development and growth of the Group or such other factors as the Board may deem appropriate.

In determining eligibility of existing or incoming employees, directors (whether executive or non-executive) or officers of the Company or any member of the Group, the Board may take into account factors including, among others, (i) his/her skill, knowledge, experience, expertise and other relevant personal qualities, (ii) educational and professional qualifications, and knowledge in the industry, (iii) performance, length of employment with the Group, nature of duties and position within the Group, (iv) his/her adherence to the Group's culture and values, or (v) the contribution and potential contribution to the development of the Group.

Service Providers include any consultant who are experts in research and development, clinical trials and academia who provides consultancy services and/or other professional services to any member of the Group in connection with drug development and clinical trials in the ordinary and usual course of business of the Group which is in the interests of the long term growth of the Group, provided that any placing agents or financial advisers providing advisory services to the Group for fundraising, mergers or acquisitions and professional services providers such as auditors or valuers who provide assurance or are required to perform their services with impartiality and objectivity should not be Service Providers.

In determining the eligibility for such consultant to be a participant of the Scheme, the Board shall, in its absolute discretion, take into account, among others, (i) the skill, knowledge and expertise of the relevant consultant including his or her capability and technical know-how; (ii) his or her experience and network in the pharmaceutical industry and the academia; (iii) his or her research and development capability as well as his or her capability and know-how as to the conduct of clinical trials; (iv) the frequency of collaboration and length of business relationship with the Group; (v) the materiality and nature of the business relationship with the Group (such as whether they relate to the core business of the Group and whether such business dealings could be readily replaced by third parties and the relevant replacement costs); (vi) the background, reputation and track record of the relevant consultant; (vii) the potential and/or actual contribution to the business affairs of the Group, and in particular, whether such consultant could bring positive impacts to the Group's business, such as drug development and/or commercialization, an increase in revenue or profits or a reduction in costs attributable to or brought by services provided by such consultant; and (viii) other factors, including but not limited to the synergy between the relevant consultant and the Group.

5.2 Offer of grant of RSUs

Subject to the limitations and conditions of this Scheme, the Board may, at its sole and absolute discretion, grant RSUs to any Selected Person on such terms and conditions as the Board thinks fit, provided that:

- (a) no RSUs shall be granted after the expiry of the term of this Scheme or after the earlier termination of this Scheme in accordance with Rule 17; and
- (b) RSUs that have lapsed in accordance with Rule 10 or for any other reasons can be re-granted by the Board.

5.3 Contents of the Grant Letter

Upon the grant of RSUs, a Grant Letter should be provided to the Selected Person and such Grant Letter shall address, among other things, the following matters:

- (a) the Selected Person's name;
- (b) the manner of acceptance of the RSU;
- (c) the number of RSUs granted and the number of underlying shares represented by the RSUs;
- (d) the vesting criteria and conditions;
- (e) the vesting schedule; and
- (f) such other terms and conditions as the Board shall determine and are not inconsistent with this Scheme.

The Grant Letter will require the Selected Person to undertake to hold the RSU on the terms on which it is granted and to be bound by the provisions of the Scheme.

The Grant Letter shall serve as evidence of the grant of the RSUs and no further certificate shall be issued to the Selected Person.

5.4 Acceptance of RSUs

A Selected Person may accept an offer of the grant of RSUs in such manner as set out in the Grant Letter. Once accepted, the RSUs are deemed granted from the date of the Grant Letter. Upon acceptance, the Selected Person becomes a Participant in this Scheme.

5.5 Information to the Trustee

The Board shall, after any RSUs have been granted and duly accepted by the Participant(s), inform the Trustee of the name(s) of the Participant(s), the number of RSUs and the number of underlying Shares that can be acquired by each Participant upon vesting of the RSUs granted to each such Participant, the vesting schedule of RSUs (if any) and other terms and conditions (if any) that RSUs are subject to as determined by the Board.

5.6 Restriction on grant of RSUs

The Board may not grant any RSUs to any Selected Persons in any of the following circumstances:

- (a) in any other circumstances where dealings by Selected Persons are prohibited under the Listing Rules, SFO or any other applicable law or regulation or where the requisite approval from any applicable regulatory authorities has not been granted, or where granting the RSUs would result in a breach by the Company, any member of our Group or any of their directors of any applicable law or regulation;
- (b) where such grant of RSUs would result in breach of the Scheme Limit, the Scheme Mandate Limit or other rules of this Scheme as set out in Rule 13;
- (c) after inside information (as defined under the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong)) has come to the Company's knowledge until (and including) the trading day after the Company has announced such information. In particular, during the period commencing 30 days immediately proceeding the earlier of:
 - (i) the date of the meeting of the Board (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and
 - (ii) the deadline for the Company to publish an announcement of its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules),

and ending on the date of the results announcement. The period during which no Award may be granted will cover any period of delay in the publication of a results announcement.

No grant of Award to a Director shall be allowed during the period prohibited by the Model Code for Securities Transactions by Directors of Listed Issuers of the Listing Rules. If any Award is proposed to be granted to a Director, it shall not be granted, accepted or vested on any day on which the financial results of the Company are published and during the period of:

- (i) 60 days immediately preceding the publication date of the annual results or, if shorter, the period from the end of the relevant financial year up to the publication date of the results; and
- (ii) 30 days immediately preceding the publication date of the quarterly results (if any) and half-year results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results.

5.7 Grant to Directors, the Senior Management and Substantial Shareholders

Each grant of Awards to a Director, the chief executive or a substantial shareholder of the Company or any of their respective associates (as defined in the Listing Rules) under this Scheme or any other share scheme of the Company or any of its subsidiaries shall be subject to approval by the independent non-executive Directors (excluding independent non-executive Director who is a proposed recipient of the grant of Awards); and each grant of Awards to a Director, the chief executive or a senior management of the Company or any of their respective associates (as defined in the Listing Rules) under this Scheme or any other share scheme of the Company or any of its subsidiaries shall be subject to the approval of the Remuneration Committee (excluding the member of the Remuneration Committee who is a proposed recipient of the grant of Awards).

Where any grant of Awards to the following person falls into any of the following:

- (a) any grant of awards to a substantial shareholder or an independent non-executive Director or any of their respective associates would result in the Shares issued and to be issued in respect of all awards granted (including awards that been cancelled but excluding any awards lapsed in accordance with the terms of the scheme) to such person in the Relevant Period representing in aggregate over 0.1% (or such other percentage as may from time to time be specified by the Stock Exchange) of the Shares in issue (excluding treasury Shares); or
- (b) any grant of awards to a Director (other than an independent non-executive director) or chief executive of the Company, or any of their associates would result in the Shares issued and to be issued in respect of all awards granted (including awards that been cancelled but excluding any awards lapsed in accordance with the terms of the scheme) to such person in the Relevant Period representing in aggregate over 0.1% (or such other percentage as may from time to time be specified by the Stock Exchange) of the Shares in issue (excluding treasury Shares),

such further grant of awards, as the case may be, must be approved by the Shareholders in such manner as required under the Listing Rules. A circular containing the information required under the Listing Rules shall be sent to the Shareholders in connection with the meeting at which their approval will be sought. The Grantee, his or her associates and all core connected persons (as defined in the Listing Rules) of the Company must abstain from voting in favour at such general meeting.

6. Vesting of RSUs

- 6.1** The Board may determine the vesting criteria, conditions and time schedule when the RSUs will vest and such criteria, conditions and time schedule shall be stated in the Grant Letter. The periods over which the Awards will vest shall not be less than 12 months or such other may exceed any minimum vesting periods prescribed from time to time by any laws, regulations or rules to which this Scheme may be subject, including the Listing Rules or regulations of any stock exchange on which the Shares may be listed and quoted. Furthermore, the Shares to be issued and allotted to a Selected Person pursuant to the vesting of any Award under this Scheme may or may not, at the discretion of the Board (or any duly authorized committee or person by the Board), be subject to any retention period.

The vesting period of Awards granted to Employee Participants (as defined under Chapter 17 of the Listing Rules) may, at the discretion of the Board (or any duly authorized committee or person by the Board), be shorter under the following circumstances: (i) grants of “make-whole” awards to new joinders to replace the share awards they forfeited when leaving their previous employers, (ii) grant to a participant whose employment is terminated due to death or disability or occurrence of any out of control event; (iii) grants of awards with performance-based vesting conditions, in lieu of time-based vesting criteria; (iv) grants that are made in batches during a year for administrative and compliance reason (may include share awards that should have been granted earlier but had to wait for a subsequent batch); (v) grant of awards with a mixed or accelerated vesting schedule such as where the awards may vest evenly over a period of 12 months; (vi) grants of awards with a total vesting and holding period of more than 12 months; and (vii) grant of awards as the year-end bonus of such Employee Participants.¹

¹ The Directors and the Remuneration Committee are of the view that the vesting period (including the circumstances in which a shorter vesting period may apply), as detailed above, enables the Company to offer competitive remuneration and reward packages to Employee Participants, on an ad hoc basis, in such circumstances that would be justified and reasonable, which is also consistent with the Listing Rules and the former practice of the Company and peer companies in the Group’s industry. In particular, Awards granted as year-end bonuses to Employee Participants may have a shorter vesting period as, despite year-end bonuses being a reward for satisfactory past performance in nature, providing year-end bonuses in the form of Awards as opposed to cash would link the value of the year-end bonuses to the future performance of the Group as well, thereby encouraging and incentivizing Employee Participants to continue committing and contributing to the development and expansion of the Group and its business. Accordingly, the above vesting period is considered appropriate and aligns with the purpose of the Scheme.

There is no general requirement for any performance target that has to be achieved before the vesting of any Award except as otherwise imposed by the Board (or any duly authorized committee or person by the Board) and stated in the offer of grant of an Award.

- 6.2** Within a reasonable time after the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, the Board shall send the Vesting Notice to each of the relevant Participants. The Vesting Notice will confirm the extent to which the vesting criteria, conditions and time schedule have been reached, fulfilled, satisfied or waived, and the number of Shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those Shares) involved.

7. Rights of Participants

- 7.1** An Award gives the Participant a conditional right upon vesting of the Award to obtain (i) the number of Shares underlying such Award held by the Trustee; or (ii) an equivalent value in cash with reference to the value of the Shares underlying such Award held by the Trustee on a date of sale ("**Date of Sale**") (being a date that the RSU Administrator determines to conduct on-market sale of such Shares once every financial year pursuant to the Scheme), less any tax, fees, levies, stamp duty and other applicable charges.

7.2 Rights on a takeover

If a general offer to acquire the Shares (whether by takeover offer, merger, or otherwise in a like manner) is made to all of the shareholders of the Company (or shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in concert with the offeror) and the general offer to acquire the Shares is approved and the offer becomes or is declared unconditional in all respects, an Employee Participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

7.3 Rights on a compromise or arrangement

If a compromise or arrangement between the Company and its shareholders or creditors is proposed in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies and a notice is given by the Company to its shareholders to convene a general meeting to consider and if thought fit approve such compromise or arrangement and such shareholders' approval is obtained, an Employee Participant's RSUs will vest immediately, even if the vesting period has not yet commenced.

7.4 Rights on voluntary winding-up

If an effective resolution is passed during the Scheme Period for the voluntary winding-up of the Company (other than for the purposes of a reconstruction, amalgamation or scheme of arrangement), all outstanding RSUs of an Employee Participant shall be treated as having vested immediately. No Shares will be transferred, and no cash alternative will be paid, to the Participant, but the Participant will be entitled to receive out of the assets available in liquidation on an equal basis with the Company's shareholders such sum as they would have received in respect of the RSUs.

8. Restrictive Covenants

- 8.1** By accepting any RSUs granted hereunder, a Participant shall be deemed to have made the Restrictive Covenants set forth in this Rule 8 (including the Non-Competition Undertaking) to and for the benefit of the Group.
- 8.2** The Participant hereby undertakes to the Group that he will not at any time whilst an employee, director, shareholder or otherwise interested in the Group (save in so far as is reasonably necessary to fulfil his duties to the Group) or at any time thereafter, directly or indirectly use or disclose or communicate to any person any information concerning the affairs, business methods, processes, systems, inventions, plans or research and development of the Group or those of its customers, clients or suppliers and which may be reasonably regarded as being confidential to the Group or to such persons (other than information which he is required to disclose by law or which is for the relevant time being in the public domain other than by reason of wrongful disclosure of the same by him) and will use his best endeavours to prevent the publication or disclosure of any such information by any third party.
- 8.3** The Participant undertakes to the Group that he will not, except with the prior written approval of the Company, be directly or indirectly concerned with or engaged or interested in any other business which is in any respect in competition with or similar to the business of the Group during his employment with the Group, save that this restriction shall not apply to any holding of Shares or other securities in the Company (the “**Non-Competition Undertaking**”).
- 8.4** *The Participant undertakes to the Group that, so far as permitted under the laws of the applicable jurisdiction(s) in which the Participant is employed:*
- (a) for so long as he is employed by the Company or any other member within the Group he will devote his full time and attention to the business of the Group and will use his best endeavours to develop the business and interests of the Group and will not be concerned with any other (competitive or other) business; and
 - (b) upon his ceasing (for any reason) to be employed by the Group he will not for a period of two (2) years from the date he ceases to be so employed, whether on his own account or on behalf of any other person, firm or company;
 - (c) solicit (in connection with any business of a type then carried on by the Group) interfere with or endeavour to entice away from any member within the Group any person, firm or company who at any time during the period of one year immediately preceding such cessation, was to his knowledge a material customer, client, supplier, agent, distributor, or an employee (not being a junior employee) or consultant (by whatever title called) of a member within the Group;

- (d) seek to interfere with the continuance of the supply of goods or services to any member within the Group or the terms of any such supply; or
- (e) carry on, engage in or be concerned or interested either as principal or agent or as a shareholder, partner or employee of any other person in any business or activity which involves the offer, sale or supply of products or services to customers in the PRC or any other territory in which the Group offers such sale or supply for the relevant time being, competes with the business in which any member within the Group is or was engaged in the twelve months prior to the date he ceases to be employed by the Group; or
- (f) use or allow the use by any third party of any name, logo or other intellectual property rights used by any member within the Group or any name or logo likely to be confused therewith otherwise than in the conduct of the business of the Group; and
- (g) deal in the Shares which would violate (i) any applicable laws, regulations and rules in any relevant jurisdictions including, without limitation, the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), other Hong Kong securities laws, and the U.S. Securities Act of 1933, as amended from time to time, and (ii) any internal policy of the Company in connection with dealing in the Shares.

8.5 The Participant undertakes to the Group that he shall not, during either the course of his employment by the Group or for a period of two (2) years from the date he ceases to be employed by the Group, make, publish, or otherwise transmit any disparaging or defamatory statements, whether written or oral, regarding the Group or its employees, products, operations, procedures, policies, business or services.

9. Rights attached to RSUs and Shares

9.1 *Rights attached to RSUs*

A Participant does not have any contingent interest in any Shares underlying the RSUs unless and until such Award is granted to the Participant. Further, a Participant may not exercise voting rights in respect of the Shares underlying the RSUs prior to their vesting and, unless otherwise specified by the Board in its entire discretion in the Grant Letter to the Participant, nor do they have any rights to any cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions from any Shares underlying the RSUs.

9.2 Rights attached to Shares

Any Shares transferred to a Participant in respect of any RSUs will be subject to all the provisions of the Articles and will rank *pari passu* with the fully paid Shares in issue on the date of the transfer or, if that date falls on a day when the register of members of the Company is closed, the first day of the reopening of the register of members, and accordingly will entitle the holders to participate in all dividends or other distributions paid or made on or after the date of transfer or, if that date falls on a day when the register of members of the Company closed, the first day of the reopening of the register of members.

10. Clawback mechanism – Lapse of RSUs

10.1 The Company can clawback any unvested RSUs by treating them as automatically lapsed immediately where:

- (a) such Participant's employment or service terminates for any reason;
- (b) such Participant breaches any restrictive covenant set out in Rule 8 (including but not limited to the Non-Competition Undertaking);
- (c) the Participant makes any attempt or takes any action to sell, transfer, assign, charge, mortgage, encumber, hedge or create any interest in favour of any other person over or in relation to any RSUs or any interests or benefits pursuant to the RSUs; or
- (d) unless otherwise determined by the Board (or any duly authorized committee or person by the Board), the performance target in relation to the vesting of any Award cannot be achieved.

10.2 If at any time, a Participant:

- (a) ceases to be an employee;
- (b) fails, during the course of his employment, to devote the whole of his time and attention to the business of the Group or to use his best endeavours to develop the business and interests of the Group;
- (c) is concerned during the course of his employment with the Group (without the prior written consent of the Company) with any (competitive or other) business other than that of the Group; and/or

- (d) is in breach of his contract of employment with or any other obligation to the Group (including without limitation the restrictive covenants set out in Rule 8 (including the Non-Competition Undertaking)),

then the Company can clawback all vested and unvested RSUs by treating them as automatically lapsed and such Participant shall have no claim whatsoever in respect of the RSUs or the underlying Shares.

PROVIDED THAT:

- (i) vested RSUs of Participants who ceased to be an employee shall remain exercisable for three months from the date on which the cessation of their employment took effect; and
- (ii) in the event of the automatic lapse of vested RSUs as a result of the breach of the Non-Competition Undertaking by the Participant or any other breach of his contract of employment with or any other obligation to the Group (the existence of such breach shall be determined by the Board at its absolute discretion), and either (a) the number of Shares underlying such Award have already been transferred to the Participant by the Trustee; or (b) an equivalent value in cash with reference to the value of the Shares underlying such Award held by the Trustee on the Date of Sale has already been transferred to the Participant by the Trustee, the Trustee shall have the right to repurchase such Shares (x) at nil consideration for the underlying Shares which are newly allotted and issued; or (y) at cost price (to be borne by the Participant and to be paid by the Trustee for and on behalf of the Participant) for the underlying Shares transferred which are received from any shareholder of the company or purchased by the Trustee on-market (with the cost price being the subscription price or purchase price actually paid by the Trustee), or upon the written instruction of the Company demand the return by the Participant of the sum of the cash equivalent so transferred to him (as the case may be). For the avoidance of doubt, the Company shall procure that sufficient funds are provided to the Trustee by whatever means as the Board may in its absolute discretion determine to enable the Trustee to satisfy its obligations in connection with the administration of this Scheme, including but not limited to conducting the repurchase in accordance with this Rule, and the Trustee shall have no liability whatsoever to anyone, including but not limited to the Company and/or any Participant in the event of the Company's failure to do so. The Trustee is under no obligation to conduct such repurchase unless and until the Trustee received the full price and all the costs and expenses in connection with or arising out of such repurchase from the Company and/or the Participants.

11. Death of a Participant

In respect of a Participant who dies at any time prior to or on the Vesting Date, all the unvested RSUs of the relevant Participant shall be automatically cancelled with effect from the date on which the Participant dies. The Board may however, in its absolute discretion, determine, within thirty (30) calendar days after the date of death, that the unvested RSUs of the relevant Employee Participant shall be vested on an accelerated basis on terms determined by the Board. In such event, subject to the Rules, the Trustee shall hold the vested RSUs upon trust and, as instructed by the Company, to transfer the same to the legal personal representatives of the Employee Participant (i) within three years of the death of the Employee Participant; or (ii) within 6 months after the date the grant of representation is obtained from relevant court (whichever is shorter).

12. Clawback mechanism – Cancellation of RSUs

12.1 The Board shall be entitled for the following causes to clawback any RSU by cancelling the same in whole or in part by giving notice in writing to the Participant stating that such RSU is thereby cancelled with effect from the date specified in such notice (the “**Cancellation Date**”):—

- (a) the Participant commits or permits or attempts to commit or permit a breach of the restriction on transferability of RSU or any terms or conditions attached to the grant of the RSU;
- (b) the Participant makes a written request to the Board for the RSU to be cancelled; or
- (c) if the Participant has, in the opinion of the Board, conducted himself in any manner whatsoever to the detriment of or prejudicial to the interests of the Company or its Subsidiary.

12.2 The Awards shall be deemed to have been cancelled with effect from the Cancellation Date in respect of any part of the Award which has not been vested as of the Cancellation Date. No compensation shall be payable upon any such cancellation, provided that the Board shall be entitled in its discretion to pay such compensation to the Participant in such manner as it may consider appropriate in any particular case.

12.3 Cancelled Awards will be regarded as utilized for the purpose of calculating the Scheme Mandate Limit and the Service Provider Sublimit. Where the Company cancels Awards and issues new ones to the same Selected Person, the issue of such new Awards may only be made under a scheme with available unissued Awards within the limit as mentioned in Rule 13.

13. Maximum number of RSUs granted under this Scheme

13.1 Scheme Limit

Subject to Rule 13.2 below, no Award shall be granted pursuant to this Scheme if as a result of such grant (assumed accepted), the aggregate number of Shares underlying all grants made pursuant to the Scheme (including Awards that been cancelled but excluding Awards that have lapsed in accordance with the rules of the Scheme) will exceed in total 3,133,526 Shares, representing 0.8993% of the total number of Shares in issue (excluding treasury Shares) on the Amendment Date (the “**Scheme Limit**”). For the avoidance of doubt, the Shares underlying the Awards under the Scheme Limit may involve existing Shares and new Shares.

The Company may seek separate approval by the Shareholders in general meeting for granting Awards beyond the Scheme Limit (as refreshed) PROVIDED THAT the Selected Person(s) of such Awards must be specifically identified by the Company before such approval is sought. A circular containing a generic description of the specified Selected Persons who may be granted such Awards, the number and terms of the Awards to be granted, the purpose of granting such Awards to the Selected Persons with an explanation as to how the terms of Awards serve such purpose and other information required by the Listing Rules shall be sent to the Shareholders.

13.2 Scheme Mandate Limit

The Shares which may be issued in respect of all Awards to be granted under this Scheme and other share schemes of the Company (including options or awards have been cancelled but excluding those lapsed in accordance with the terms of the respective share schemes) shall not exceed 29,113,683 Shares (representing 8.3553% of the number of Shares in issue (excluding treasury Shares) on the Amendment Date) (the “**Scheme Mandate Limit**”).

13.3 Service Provider Sublimit

Subject to the Scheme Limit and the Scheme Mandate Limit, the maximum number of Shares in respect of which Awards under the Scheme may be granted to the Service Providers and yet to be vested (including options or awards have been cancelled but excluding those lapsed in accordance with the terms of the respective share schemes) is 3,483,089 Shares, representing one per cent (1%) of the Shares in issue (excluding treasury Shares) as at the Amendment Date (the “**Service Provider Sublimit**”).

13.4 *Renewal of Scheme Limit, Scheme Mandate Limit and/or Service Provider Sublimit*

Subject to Rules 13.1, 13.2 and 13.3 the Company may seek approval of the Shareholders in general meeting for refreshing the Scheme Limit, the Scheme Mandate Limit and/or the Service Provider Sublimit every three years after the Amendment Date or the shareholder approval date of the last refreshment, as the case may be. However, the Scheme Mandate Limit as refreshed shall not exceed 10% of the total number of Shares in issue (excluding treasury Shares) as at the Amendment Date. Any refreshment within any three year period must be approved by shareholders of the Company subject to the following or other terms under the applicable listing rules and laws and regulations: (i) any controlling shareholders (as defined in the Listing Rules) and their associates (or if there is no controlling shareholders, Directors (excluding the independent non-executive Directors) and the chief executive of the Company and their respective associates) must abstain from voting in favor of the relevant resolutions at the general meeting; and (ii) the Company must comply with the requirement of independent shareholder approval. A circular containing the information required under the Listing Rules shall be sent to the Shareholders in connection with the meeting at which their approval will be sought.

The maximum number of Shares referred to in this Rule 13 shall be adjusted in the event of any alteration in the capital structure of the Company in accordance with Rule 14.

13.5 *Individual Limit*

The total number of Shares issued and to be issued in respect of all the Awards granted to each Eligible Person under the Scheme and any other share schemes of the Group (including Awards that been cancelled but excluding any Awards lapsed in accordance with the terms of Scheme or any other share schemes of the Group) in any twelve (12) month period up to and including the date of such grant (the “**Relevant Period**”) shall not exceed 1% of the Shares in issue (excluding treasury Shares) (the “**Individual Limit**”) from time to time. Any further grant to a Selected Person which would result in the Shares issued and to be issued exceeding the Individual Limit shall be subject to the Shareholders’ approval in general meeting with such Selected Persons and his or her close associates (as defined under the Listing Rules, or his or her associate if the Selected Person is a connected person) abstaining from voting. A circular containing the information required under the Listing Rules shall be sent to the Shareholders. The number and terms (including the subscription price) of the Awards to be granted to such Selected Person must be fixed before the Shareholders’ approval is sought and the date of the meeting of the Board for proposing such further grant of Awards should be taken as the Grant Date for the purpose of calculating the subscription price, as applicable.

14. Reorganization of capital structure

In the event of any capitalization issue, bonus issue, rights issue, consolidation, sub-division of shares or reduction of the share capital of the Company, the Board may make such equitable adjustments, designed to protect the Participants' interests, to the number of Shares underlying the outstanding RSUs or to the amount of the equivalent value, as it may deem appropriate in accordance with the guidance of the Stock Exchange issued from time to time and as the auditors or the independent financial adviser of the Company retained for such purpose shall certify in writing to the Board to be in their opinion fair and reasonable, PROVIDED THAT any alteration shall be made on the basis that the proportion of the issued share capital of the Company to which a Selected Person is entitled after such alteration shall remain the same, rounded to the nearest whole Share, as that to which he or she was entitled before such alteration, and that the aggregate subscription price (if any) payable by a Selected Person on the full vesting of any Awards after such alteration shall remain as nearly as possible the same (but shall not be greater than) as it was before such event, but no such alteration shall be made the effect of which would be to enable any Share to be issued at less than its nominal value, or to give the advantage of Selected Person without specific prior Shareholders' approval. No adjustment will be required in circumstances where there is an issue of Shares or other securities of the Group as consideration in a transaction.

In addition, in respect of any such alteration as provided in this Rule 14 after the Amendment Date other than any made on a capitalization issue, the auditors or the independent financial adviser of the Company retained for such purpose must confirm in writing to the Board that the alteration satisfy the requirements of the relevant provision of the Listing Rules and any guidance letter issued by the Stock Exchange from time to time.

The capacity of the auditors or the independent financial adviser of the Company (as the case may be) in this Clause 14 is that of experts and not of arbitrators and their certification shall, in the absence of manifest error, be final and binding on the Company and the Grantees.

The costs of the auditors or the independent financial adviser of the Company (as the case may be) shall be borne by the Company.

To the extent not otherwise determined by the Board, the method of adjustment of the number of Awards to the extent outstanding is set out as below:

Capitalization issue

$Q = Q_0 \times (1 + n)$ Where: "Q₀" represents the number of Awards before the adjustment; "n" represents the ratio per Share resulting from the capitalization issue; "Q" represents the number of Awards after the adjustment.

Rights issue

$$Q=Q_0 \times P_1 \times (1 + n) \div (P_1 + P_2 \times n)$$

Where: “Q₀” represents the number of Awards before the adjustment; “P₁” represents the closing price of the Shares as at the record date; “P₂” represents the subscription price of the rights issue; “n” represents the ratio of the rights issue allotment; “Q” represents the number of Awards after the adjustment.

Consolidation of Shares or share subdivision or reduction of the share capital

$$Q=Q_0 \times n$$

Where: “Q₀” represents the number of Awards before the adjustment; “n” represents the ratio of share consolidation or share subdivision or reduction of share capital; “Q” represents the number of Awards after the adjustment.

No price adjustment shall be made to the Awards in the event of any capitalization issue, bonus issue, rights issue, consolidation, sub-division of shares or reduction of the share capital of the Company as no price is payable for the grant of Awards and the Awards also have no exercise price.

15. Disputes

The Board shall determine any question of interpretation and settle any dispute arising under or in connection with this Scheme. In such matters, the Board’s decision shall be final.

16. Amendment of this Scheme

16.1 Subject to Rule 16.2 below and the compliance with the Listing Rules, save for any alterations to this Scheme which are of a material nature of any alterations to the provisions relating to the matters set out in Rule 17.03 of the Listing Rule to the advantage of the Selected Persons must be approved by the Shareholders in general meeting, the Board may amend any of the provisions of the Scheme (including without limitation to amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of this Scheme, which are not found in Chapter 17 of the Listing Rules) at any time.

16.2 Subject to compliance with the Listing Rules, any change to the terms of the Awards granted to a Selected Person must be approved by the Board, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, as the case may be, if the initial grant of the Awards was approved by the Board, the Remuneration Committee, the independent non-executive Directors and/or the shareholders of the Company, correspondingly. This requirement does not apply to the alterations take effect automatically under the existing terms of this Scheme. The amended terms of this Scheme must still comply with the applicable provisions of the Listing Rules.

17. Termination of this Scheme

The Board may terminate this Scheme at any time before the expiry of the Scheme Period. The provisions of this Scheme shall remain in full force and effect in respect of RSUs which are granted pursuant to these Rules prior to the termination of the operation of this Scheme. No further Award shall be granted after such termination; however, all Awards granted prior to such termination and not vested on the date of termination shall remain valid. The Company or relevant member of the Group shall notify the Trustee and all Participants of such termination and of how any property held by the Trustee on trust for the Participants (including, but not limited to, any Shares held) and the outstanding RSUs shall be dealt with.

18. Miscellaneous

18.1 Costs of this Scheme

The Company shall bear the costs of establishing and administering this Scheme. For the avoidance of doubt, all stamp duty and/or transfer tax or duty and any other charges payable upon the transfer of the Shares to the Participant upon vesting of the RSUs shall be borne by the Participant.

18.2 Notices

- (i) Any notice or other document which has to be given to a Selected Person or a Participant under or in connection with this Scheme may be delivered to the Selected Person or the Participant or sent by post or facsimile transmission or e-mail to him at his home postal address, home or work e-mail address or facsimile number according to the records of his employing company or such other address as the Company reasonably considers appropriate.
- (ii) Any notice or other document which has to be given to the Company under or in connection with this Scheme may be delivered or sent by post to it at its registered office (or such other place as the Board may from time to time decide and notify to the Participants and/or the Trustee) or by facsimile transmission to the central facsimile number of the Company or by e-mail.

- (iii) Any notice or other document which has to be given to the Trustee under or in connection with this Scheme may be delivered or sent by post to it at its registered office (or such other place as the Trustee may from time to time decide and notify to the Company and/or the Participants) or by facsimile transmission to the central facsimile number of the Trustee or the work e-mail address of a designated person of the Trustee as notified by the Trustee to the Company.
- (iv) Any notice or other document if given by a Selected Person or a Participant shall be irrevocable and shall not be effective until actual receipt by the Trustee or the Company (as the case may be).
- (v) Notices sent by post will be deemed to have been given by the Company or the Trustee on the first day after the date of posting, and by the Participant on the date of receipt by the Board or the Trustee (as the case may be). Notices served by hand will be deemed to be served when delivered.

18.3 *Responsibility for obtaining consents*

A Participant shall be responsible for obtaining any governmental or other official consent that may be required in order to permit the acceptance or vesting of the RSUs. The Company and the Trustee shall not be responsible for any failure by a Participant to obtain any such consent and shall not be liable for any cost incurred in obtaining such consent.

18.4 *Responsibility for tax etc.*

Subject to Rule 18.1, the Company and the Trustee shall not be liable for any tax or other liability to which a Participant may become subject as a result of his or her participation in this Scheme.

18.5 *No other rights*

This Scheme shall not confer on any person any legal or equitable rights against the Company directly or indirectly or give rise to any cause of action at law or in equity against the Company.

18.6 *Discretionary Scheme*

This Scheme is discretionary and shall not form part of any contract (whether a contract of employment or otherwise) between the Company or any member of the Group and any Eligible Person and/or Selected Person. The rights and obligations of any Eligible Person under the terms of his/her office or employment shall not be affected by his participation in this Scheme. This Scheme shall give an Eligible Person no additional rights to compensation or damages in consequence of the termination of his/her office or employment.

18.7 *Power to adopt operational rules*

The Board may from time to time adopt such operational rules as it may deem fit for the purpose of giving effect to or implementing this Scheme (including but not limited to formulating rules which restrict the vesting of the RSUs granted or to be granted or otherwise impose restrictions on the Participant), provided that such rules do not conflict with these Rules or contravene any of the applicable laws or regulations.

18.8 *Governing law and jurisdiction*

This Scheme and all RSUs granted under it shall be governed by and construed in accordance with Hong Kong law.

The Hong Kong courts shall have the exclusive jurisdiction to determine any claim, dispute or difference arising out of or in connection with this Scheme or any RSUs granted under it.

CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN REDACTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.**

AMENDED AND RESTATED LICENSE AGREEMENT

This Amended and Restated Patent License Agreement (“Agreement”) is effective as of August 12, 2025 (the “Effective Date”), between Ascentage Pharma Group (“LICENSEE”) having the address in Article 13 below, and the Regents of the University of Michigan, a constitutional corporation of the state of Michigan (“MICHIGAN”). This Agreement replaces and supersedes the License Agreement- University of Michigan Files [***] between LICENSEE and MICHIGAN with an effective date of December 1, 2010 and amended May 30, 2013, February 2, 2016, May 10, 2017, June 1, 2017, August 9, 2018, December 17, 2018, January 10, 2019 and November 30, 2020. LICENSEE and MICHIGAN agree as follows:

ARTICLE 1 - DEFINITIONS

1.1 “CHINA” means mainland China, Hong Kong, Macau and Taiwan.

1.2 “FIELD OF USE” means all fields.

1.3 “FIRST COMMERCIAL SALE” the first invoiced sale for monetary value for use or consumption by the end user of such LICENSED PRODUCT after regulatory approval for such LICENSED PRODUCT has been obtained in the TERRITORY and where the sale results in a recordable NET SALES in accordance with applicable accounting standard of LICENSEE, provided that (a) any indigent patient, clinical trial or any compassionate or named patient, charitable or humanitarian programs shall not be considered a FIRST COMMERCIAL SALE and (b) sale of a LICENSED PRODUCT under this Agreement by a by or on behalf of LICENSEE or its Affiliates or its or their sublicensees (“LICENSEE Party” to another LICENSEE PARTY shall not be considered a FIRST COMMERCIAL SALE unless such LICENSEE Party is the end user of such LICENSED PRODUCT and such sale results in a recordable NET SALES..

1.4 “GROSS SUBLICENSING REVENUES” means all revenue or consideration due to LICENSEE from a SUBLICENSEE in consideration for rights under or relating to the PATENT RIGHTS (including, but not limited to, license issue fees, maintenance or annual minimum fees, amounts based on product sales, milestone payments, other royalties) whether received in cash or equity. GROSS SUBLICENSING REVENUES shall not include amounts that a SUBLICENSEE pays to LICENSEE that are specifically identified for research and development, any indigent patient, or any compassionate or named patient, charitable or humanitarian programs or where LICENSEE is the end user of such LICENSED PRODUCT and such sale is not a recordable NET SALES.

1.5 “LICENSED PROCESS(ES)” means any process or method that, but for this Agreement, comprises an infringement of (including contributory or inducement), or is covered by, an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS or uses a LICENSED PRODUCT.

[***]

1.6 “LICENSED PRODUCT(S)” means any product that: (a) but for this Agreement comprises an infringement of (including contributory or inducement), or is covered by, an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS in the country in which any such product or product part is made, used, imported, offered for sale or sold; or (b) is manufactured by using a LICENSED PROCESS or is employed to practice a LICENSED PROCESS.

1.7 “NCE” means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act as defined in 21 CFR 314.108.

1.8 “NET SALES” means the amount billed or invoiced, and if any amount is not billed or invoiced, the amounts received, on sales, rental or lease, however characterized, by LICENSEE of LICENSED PRODUCTS and uses or licenses of LICENSED PROCESSES, less the following deductions (but only to the extent such sums are otherwise included in NET SALES and are not obtained in view of other consideration received by LICENSEE):

- (a) cash discounts actually granted to customers in such invoices for sales or lease of LICENSED PRODUCTS, but only in amounts customary in the trade;
- (b) sales, tariff duties and/or use taxes separately stated in such bills or invoices with reference to particular sales and actually paid by LICENSEE to a governmental unit;
- (c) actual freight expenses between LICENSEE and customers, to the extent such expenses are not charged to or reimbursed by customers; or
- (d) amounts actually refunded or credited on returns.

Where LICENSEE receives any consideration other than cash for such transactions, fair market cash value for such consideration, to be agreed upon by the parties hereto, shall be included in NET SALES.

1.9 “PATENT RIGHTS” means MICHIGAN’S legal rights under the patent laws of the United States or relevant foreign countries for all of the following:

- (a) the following United States and foreign patent(s) and/or patent application(s), and divisionals, continuations (except continuations-in-part), and foreign counterparts of the same:

[***]

and

[***]

United States and foreign patent(s) and/or patent application(s) (and divisionals, continuations, (except continuations-in-part), and foreign counterparts (including, for the sake of clarity, all foreign national cases claiming priority to the identified PCT applications of the same) which are directed to inventions disclosed to the MICHIGAN Innovation Partnerships and specifically described and enabled in the invention reports of Innovation Partnerships designated by

(b) United States and foreign patents issued from the applications listed in subparagraph 1.7(a) above, including any reissued or reexamined patents based upon the same.

1.10 ROYALTY PERIOD(S)” means the six-month periods ending on the last days of June and December each year.

1.11 “ROYALTY TERM” means until the expiration of the last to expire of the PATENT RIGHTS.

1.12 “SUBLICENSEE(S)” means any person or entity sublicensed, or granted an option for a sublicense, by LICENSEE under this Agreement.

1.13 “TERRITORY” means worldwide.

ARTICLE 2 - GRANT OF LICENSE

2.1 MICHIGAN hereby grants to LICENSEE an exclusive license under the PATENT RIGHTS, with the right to grant sublicenses, both subject to the terms and conditions of this Agreement, in the FIELD OF USE and the TERRITORY to make, have made, import, use, market, offer for sale and sell LICENSED PRODUCTS and to practice LICENSED PROCESSES.

2.2 Without limiting any other rights it may have, MICHIGAN specifically reserves the right to practice the PATENT RIGHTS for research, public service, internal (including clinical) and/or educational purposes, and the right to grant the same limited rights to other non-profit research institutions.

2.3 LICENSEE agrees that LICENSED PRODUCTS used, leased or sold in the United States shall be manufactured substantially in the United States.

2.4 The licenses granted in this Agreement are subject to any rights required to be granted under prior research or sponsorship agreements, or retained by the U.S. government, for example in accordance with Chapter 18 or Title 35 of U.S.C. 200-212 and the regulations thereunder (37 CFR Part 401), when applicable. LICENSEE agrees to comply in all respects, and shall provide MICHIGAN with all reasonably requested information and cooperation for MICHIGAN to comply with applicable provisions of the same and any requirements of any contracts between MICHIGAN and any agency of the U.S. government that provided funding for the subject matter covered by the PATENT RIGHTS.

ARTICLE 3 - CONSIDERATION

3.1 LICENSEE shall pay royalties to MICHIGAN as follows:

(a) Omitted.

Royalty rate on Total Annual NET SALES of LICENSED
PRODUCTS on each NCE in CHINA

Annual NET SALES up to [***]	[***]
Annual NET SALES of [***]	[***]
Annual NET SALES over [***]	[***]

Royalty rate on Total Annual NET SALES of LICENSED
PRODUCTS on each [***] in all other territories:

Annual NET SALES up to [***]	[***]
Annual NET SALES of [***]	[***]
Annual NET SALES of [***]	[***]
Annual NET SALES over [***]	[***]

LICENSEE shall pay Royalties to MICHIGAN during the entire Royalty Term, on a LICENSED PRODUCT-by-LICENSED PRODUCT and country-by-country basis and this provision shall survive any termination of this Agreement.

If LICENSEE makes any NET SALES to any party affiliated with LICENSEE, or in any way directly or indirectly related to or under the common control with LICENSEE, at a price less than the regular price charged to other parties, the Royalties payable to MICHIGAN shall be only apply if those sales are booked at NET SALES by LICENSEE and the Royalty shall be computed on the basis of the price paid by commercial payors.

(b) LICENSEE shall pay the following percentage of GROSS SUBLICENSING REVENUES to MICHIGAN.

- (1) [***] if the sublicense agreement is signed before the FDA, or foreign equivalent, approves the LICENSEE or SUBLICENSEE's IND on a LICENSED PRODUCT included in such sublicense agreement;
- (2) [***] if the sublicense agreement is signed after IND but before dosing the first patient in a Phase II clinical trial conducted by LICENSEE or SUBLICENSEE on a LICENSED PRODUCT in such sublicense agreement; and
- (3) [***] if the sublicense agreement is signed after dosing the first patient in a Phase II clinical trial conducted by LICENSEE or SUBLICENSEE on a LICENSED PRODUCT in such sublicense agreement.

In the event that GROSS SUBLICENSING REVENUES includes non-cash consideration (i.e., that LICENSEE enters into a sublicense in which a SUBLICENSEE is to pay LICENSEE consideration other than cash), MICHIGAN shall receive its percentage according to the following. In each such instance, LICENSEE shall direct and require SUBLICENSEE to directly transfer to MICHIGAN its share of the total non-cash consideration to be otherwise transferred to LICENSEE within ten (10) days after said SUBLICENSEE transfers said non-cash consideration to LICENSEE. For example, if a SUBLICENSEE agrees to provide consideration in the form of stock in one or more tranches, LICENSEE shall direct and require SUBLICENSEE to directly transfer to MICHIGAN those number of shares of stock representing the appropriate percentage above by said deadline. LICENSEE shall make such transfer pursuant to and subject in substance to the terms of the form of Stock Transfer Agreement attached hereto as Appendix A (the "EQUITY TRANSFER AGREEMENT").

(c) LICENSEE shall pay to MICHIGAN annual license maintenance fee ("Annual Fee"). This Annual Fee is accrued on June 30 of the years specified below, and is payable with the semi-annual report for the ROYALTY PERIOD in which the Annual Fee accrues. This Annual Fee is non-creditable and non-refundable. The Annual Fees are:

(i) Beginning in 2018 or in the calendar year of completion of [***] clinical trial for [***], whichever is earlier: [***];

(ii) Beginning one year after [***] or 2020, whichever is earlier: [***];

(d) LICENSEE shall pay milestone payments as follows:

(i) [***] upon initiation of [***] trials for each [***];

(ii) [***] upon [***] for each [***];

(iii) [***] upon completion of [***] trials for each [***] in a country other than [***];

(iv) [***] upon completion of [***] clinical trial for each [***] in a country other than [***]; and

(v) [***] upon registration of each [***] in the first major geographic market other than [***].

Milestone payments, except for registration payment, are non-refundable and non- creditable against future royalties, with the exception that the registration payment is fully creditable against future royalties.

3.2 LICENSEE shall be responsible for the payment of all taxes, duties, levies, and other charges imposed by any taxing authority with respect to the royalties payable to MICHIGAN under this agreement. Should LICENSEE be required under any law or regulation of any government entity or authority to withhold or deduct any portion of the payments on royalties due to MICHIGAN, then the sum payable to MICHIGAN shall be increased by the amount necessary to yield to MICHIGAN an amount equal to the sum it would have received had no withholdings or deductions been made. MICHIGAN shall cooperate reasonably with LICENSEE in the event LICENSEE elects to assert, at its own expense, MICHIGAN's exemption from any such tax or deduction.

3.3 LICENSEE is not obligated to pay multiple Royalties if any LICENSED PRODUCT or LICENSED PROCESS is covered by more than one claim of PATENT RIGHTS or the same LICENSED PRODUCT is covered by claims in two or more countries.

3.4 Royalty payments shall be made to “The Regents of the University of Michigan” in United States dollars. Payments drawn directly on a U.S. bank may be made by either check to the address in Article 13 or by wire transfer. Any payment drawn on a foreign bank or foreign branch of a U.S. bank shall be made only by wire transfer. Wire transfers shall be made in accordance with the following or any other instructions as may be specified by [***]. In computing Royalties, LICENSEE shall convert any revenues it receives in foreign currency into its equivalent in United States dollars at the most recent exchange rate published in the Wall Street Journal on the last business day of the ROYALTY PERIOD during which such payments are received by LICENSEE, or at such other exchange rate as the parties may agree to in writing.

3.5 Royalty payments shall be made on a semi-annual basis with submission of the reports required by Article 4. All amounts due under this Agreement, including amounts due for the payment of patent expenses, shall, if overdue, be subject to a charge of interest compounded monthly until payment, at a per annum rate of five percent (5%) above the prime rate in effect at the JP Morgan Chase Bank, N.A. or its successor bank on the due date (or at the highest allowed rate if a lower rate is required by law) or \$250, whichever is greater. The payment of such interest shall not foreclose MICHIGAN from exercising any other rights it may have resulting from any late payment. LICENSEE shall reimburse MICHIGAN for the costs, including reasonable attorney fees, for expenses paid in order to collect any amounts overdue more than 120 days.

3.6.1 Omitted.

3.6.2 Omitted.

ARTICLE 4- REPORTS

4.1 Until the FIRST COMMERCIAL SALE, LICENSEE shall provide to MICHIGAN a written annual report on or before July 30 of each year. The annual report shall include: reports of progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the preceding twelve (12) months, and plans for the coming year. LICENSEE also shall report to MICHIGAN the date of first sale or lease of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country within thirty (30) days of occurrence.

4.2 After the FIRST COMMERCIAL SALE, LICENSEE shall provide semi-annual reports to MICHIGAN. By each July 30 and January 31 (i.e., within one month after each ROYALTY PERIOD closes, including the close of the ROYALTY PERIOD immediately following any termination of this Agreement), LICENSEE shall report to MICHIGAN for that ROYALTY PERIOD:

- (a) number of LICENSED PRODUCTS sold, leased, or distributed, however characterized, by LICENSEE and each SUBLICENSEE.
- (b) NET SALES, excluding the deductions provided therefor, of LICENSED PRODUCTS sold, distributed, used, rented, leased, or licensed, however characterized, by LICENSEE and all SUBLICENSEES.
- (c) accounting for all LICENSED PROCESSES used, sold, or licensed, however characterized, by LICENSEE and all SUBLICENSEES included in NET SALES, excluding the deductions therefor. (d) deductions applicable as provided in the definition for NET SALES above.
- (e) amounts due on payments from SUBLICENSEE under Paragraph 3.1 above, including supporting documentation, including but not limited to any non-cash consideration owed by SUBLICENSEE to LICENSEE.
- (f) foreign currency conversion rate and calculations (if applicable) and total royalties due.
- (g) names, addresses, and U.S.P.T.O. Entity Status (as discussed in Paragraph 4.5) of all SUBLICENSEES having a sublicense or option therefor any time during the particular ROYALTY PERIOD.
- (h) for each sublicense or amendment thereto completed in the particular ROYALTY PERIOD (including agreements under which LICENSEE will have LICENSED PRODUCTS made by a third party), the date of each agreement and amendment, the territory of the sublicense, the scope of the sublicense, and the nature, timing and amounts of all fees and royalties to be paid thereunder.
- (i) any milestone (under Article 3 or Article 5) that has been achieved, and any milestone that was due during the ROYALTY PERIOD but not achieved, specifying each milestone and whether or not it was achieved.

LICENSEE shall include the amount of all payments due, and the various calculations used to arrive at those amounts, including the quantity, description (nomenclature and type designation as described in Paragraph 4.3 below), country of manufacture and country of sale or use of LICENSED PRODUCTS and LICENSED PROCESSES. LICENSEE shall direct its authorized representative to certify that reports required hereunder are correct to the best of LICENSEE's knowledge and information. Failure to provide reports as required under this Article 4 shall be a material breach of this Agreement.

If no payment is due, LICENSEE shall so report to MICHIGAN that no payment is due.

4.3 LICENSEE shall promptly establish and consistently employ a system of specific nomenclature and type designations for LICENSED PRODUCTS and LICENSED PROCESSES to permit identification and segregation of various types where necessary. LICENSEE shall consistently employ, and shall require SUBLICENSEES to consistently employ, the system when rendering invoices thereon and shall inform MICHIGAN, or its auditors, when requested, as to the details concerning such nomenclature system, all additions thereto and changes therein.

4.4 LICENSEE shall keep, and shall require SUBLICENSEES to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. LICENSEE shall, and it shall require all SUBLICENSEES and those making LICENSED PRODUCTS, to: (a) open such records for inspection upon reasonable notice during business hours, and no more than once per year, by either MICHIGAN auditor(s) or an independent certified accountant selected by MICHIGAN, for the purpose of verifying the amount of payments due; and (b) retain such records for six (6) years from date of origination.

The terms of this Article shall survive any termination of this Agreement. MICHIGAN is responsible for all expenses of such inspection, except that if any inspection reveals an underpayment greater than five percent (5%) of royalties due MICHIGAN, then LICENSEE shall pay all expenses of that inspection and the amount of the underpayment and interest to MICHIGAN within twenty-one (21) days of written notice thereof. LICENSEE shall also reimburse MICHIGAN for reasonable expenses required to collect the amount underpaid.

4.5 So that MICHIGAN may pay the proper U.S. Patent and Trademark Office fees relating to the PATENT RIGHTS, if LICENSEE, any company related to LICENSEE or SUBLICENSEE (including optionees) does not qualify as a "Small Entity" under U.S. patent laws, LICENSEE shall notify MICHIGAN immediately. The parties understand that the changes to LICENSEE's, SUBLICENSEE's, or optionees' businesses that might affect entity status include: acquisitions, mergers, hiring of a total of more than 500 total employees, sublicense agreements, and sublicense options.

4.6 Affordable Access Plan. Within three (3) months of receiving FDA (or its foreign equivalent's) approval of a LICENSED PRODUCT, LICENSEE will provide MICHIGAN with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), LICENSEE agrees to discuss such reasoning with MICHIGAN in good faith within one (1) month thereafter ("Initial Discussion") and, if following such Initial Discussion MICHIGAN concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to MICHIGAN within three (3) months of such Initial Discussion. The "Affordable Access Plan" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in the U.S., as defined by the Department of Health and Human Services, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that MICHIGAN can make available to third parties: (a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory"); (b) LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations; and (c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S. Within thirty (30) days of MICHIGAN's request (but no more often than once annually), LICENSEE agrees to confer with MICHIGAN to review LICENSEE'S progress, and to consider in good faith any modifications suggested by MICHIGAN, with respect to its Affordable Access Plan ("Progress Discussions").

ARTICLE 5 - DILIGENCE

5.1 LICENSEE shall use commercially reasonable efforts to bring a full scope of LICENSED PRODUCTS to market or one or more LICENSED PROCESSES to commercial use through a thorough, vigorous and diligent program for exploiting the PATENT RIGHTS and to continue active, diligent marketing efforts throughout the life of this Agreement. LICENSEE has the responsibility to do all that is necessary to obtain and retain any governmental approvals to manufacture and/or sell LICENSED PRODUCTS and/or use LICENSED PROCESSES for all relevant activities of LICENSEE and SUBLICENSEES.

5.2 With respect to each Invention Report identified below and/or in any future amendment to this Agreement, LICENSEE agrees to reach the following commercialization and research and development milestones with respect to LICENSED PRODUCTS that are covered by PATENT RIGHTS that are added to this Agreement on or after January 1, 2024 (together the "MILESTONES") by the following dates:

1. Nominate clinical development lead compound [***] including non-GMP scale-up production, pre-formulation, non-GLP preclinical toxicity and pharmacokinetic studies of the lead compounds completed for such selection within thirty-six (36) months after the date the of the PATENT RIGHTS covering such [***] is added into this Agreement.
2. IND filing with US FDA or equivalent regulatory agency of foreign countries such as NMPA in CHINA for each NCE project, including GMP scale-up production and GLP toxicology studies of the lead compounds completed for such selection with eighteen (18) months of selection of the clinical development lead compounds.
3. Initiate [***] trials for each [***] within twelve (12) months of [***] filing with appropriate regulatory agency.
4. Initiate [***] clinical trials for each [***] within twelve (12) months of successful completion of [***] trials.
5. Initiate [***] clinical trials for each [***] with twelve (12) months of successful completion of [***].

For clarity this Section 5.2 does not apply to any LICENSED PRODUCT associated only with a PATENT RIGHT that was included in this Agreement prior to January 1, 2024.

5.3 LICENSEE must achieve each MILESTONE on or before the deadline dates indicated and MICHIGAN shall have the sole discretion to determine the validity of a MILESTONE being reached. LICENSEE shall notify MICHIGAN within ten (10) days after each such deadline as to whether or not such MILESTONE was met. If LICENSEE fails to meet any MILESTONE under this Article by the date of any MILESTONE deadline, LICENSEE will be deemed to be in material breach of this Agreement, and MICHIGAN may terminate the Agreement effective on thirty (30) days notice, unless LICENSEE achieves the MILESTONE within this thirty day period. Notwithstanding, MICHIGAN may terminate this Agreement immediately if LICENSEE fails to achieve a MILESTONE by the indicated date and does not provide the notice to MICHIGAN referred to above.

ARTICLE 6 - SUBLICENSING

6.1 LICENSEE shall notify MICHIGAN in writing of every sublicense agreement and each amendment thereto within thirty (30) days after their execution, and indicate the name of the SUBLICENSEE and its number of employees, the territory of the sublicense, the scope of the sublicense, and the nature, timing and amounts of all fees and royalties to be paid thereunder. Upon request, LICENSEE shall provide MICHIGAN with a copy of sublicense agreements.

6.2 LICENSEE shall not receive from SUBLICENSEES anything of value other than cash payments in consideration for any sublicense under this Agreement, without the express prior written permission of MICHIGAN.

6.3 Each sublicense granted by LICENSEE under this Agreement shall provide for its termination upon termination of this Agreement. Each sublicense shall terminate upon termination of this Agreement unless LICENSEE has previously assigned its rights under the sublicense to MICHIGAN and MICHIGAN has agreed at its sole discretion in writing to such assignment.

6.4 LICENSEE shall require that all sublicenses:

(1) be consistent with the terms and conditions of this Agreement;

(2) contain the SUBLICENSEE'S acknowledgment of the disclaimer of warranty and limitation on MICHIGAN's liability, as provided by Article 9 below; and

(3) contain provisions under which the SUBLICENSEE accepts duties at least equivalent to those accepted by the LICENSEE in the following Paragraphs: 4.4 (duty to keep records); 4.5 (duty regarding Patent Office fees); 9.4 (duty to avoid improper representations or responsibilities); 10.1 (duty to defend, hold harmless, and indemnify MICHIGAN); 10.3 (duty to maintain insurance); 14.5 (duty to properly mark LICENSED PRODUCTS with patent notices); 14.7 (duty to restrict the use of MICHIGAN's name); 14.8 (duty to control exports).

ARTICLE 7 -PATENT APPLICATIONS AND MAINTENANCE

7.1 MICHIGAN has the right to control all aspects of filing, prosecuting, and maintaining all of the patents and patent applications that form the basis for the PATENT RIGHTS, interferences, and disputes (including litigation) regarding inventorship. LICENSEE shall fully cooperate in such activities.

7.2 MICHIGAN shall notify LICENSEE of all information received by MICHIGAN relating to the filing, prosecution and maintenance of the patents and patent applications which form the basis of the PATENT RIGHTS, and shall make reasonable efforts to allow LICENSEE to review, comment, and advise upon such information. LICENSEE agrees to hold such information confidential and to use the information provided by MICHIGAN only for the purpose of advancing MICHIGAN's PATENT RIGHTS.

7.3 LICENSEE shall reimburse MICHIGAN for all fees and costs relating to the activities described in this Article. Such reimbursement shall be made within thirty (30) days of receipt of MICHIGAN's invoice and shall be subject to the interest and other requirements specified in Paragraph 3.5 above.

ARTICLE 8 – ENFORCEMENT

8.1 Each party shall promptly advise the other in writing of any acts of potential infringement of the PATENT RIGHTS by a third party (the "Notice"), and provide any evidence thereof at the request of the other party. After the Notice, LICENSEE shall use diligent efforts to eliminate such infringement without litigation, including, if reasonable, by attempting communications with such third party after consulting MICHIGAN. MICHIGAN's Innovation Partnerships shall provide reasonable assistance to advance such efforts. Beginning at the time of the Notice, each party shall reasonably consider and discuss entering into a common interest agreement and/or joint legal representation.

8.2 To the extent the described activities do not result in the elimination of such infringement, LICENSEE shall share with MICHIGAN, subject to appropriate confidentiality and joint privilege/common interest agreement(s) to be negotiated in good faith between the parties, the complete results of the LICENSEE's diligence related to the potential infringement identified above (including, but not limited to, a detailed infringement analysis), as may be updated from time to time. The parties shall jointly identify a strategy with respect to addressing the infringement.

8.3 Subject to the other terms in this Article and LICENSEE being in compliance with the other terms of this Agreement (unless otherwise agreed to by MICHIGAN), LICENSEE has the right to direct that the parties enforce the PATENT RIGHTS against infringement by other parties within the TERRITORY and the FIELD OF USE, including those prior to the EFFECTIVE DATE. LICENSEE's right begins upon the earlier of (a) the FIRST COMMERCIAL SALE or (b) LICENSEE making a bona fide Investigational Device Exemption or Investigational New Drug Application (or equivalent) filing with the United States Food and Drug Administration or equivalent agency in Europe, China, or Japan (to the extent included within the TERRITORY). If MICHIGAN is a necessary or indispensable party under applicable law in order for a given reasonable lawsuit to enforce the PATENT RIGHTS within the LICENSED TERRITORY and FIELD OF USE to proceed, MICHIGAN shall join in such lawsuit, subject to the other terms of this Article. Each party may grant or delegate to third parties the right to enforce hereunder, and within the LICENSED TERRITORY and FIELD OF USE, only with the express written permission of the other party.

8.4 With respect to the filing and prosecution of infringement lawsuits, the parties agree to negotiate in good faith to jointly select lead counsel (to be a large, nationally recognized litigation firm) and local counsel (if lead counsel does not have an office in the location of the suit) that would represent both parties in the infringement lawsuit, each counsel to have demonstrated significant experience in the applicable legal work. LICENSEE shall reimburse MICHIGAN for out-of-pocket expenses incurred in connection with MICHIGAN's activities under this Article, including but not limited to outside counsel expenses incurred prior to, during, and in the settlement of such litigation, within 30 days after receiving an invoice from MICHIGAN therefor. Upon the determination to file suit or retain of counsel in accordance with this Article, or at any other time requested by a party, the parties shall negotiate in good faith a written agreement consistent with the foregoing and this Agreement specifying any further reasonable details. LICENSEE shall indemnify and hold harmless MICHIGAN with respect to any claims asserted by an alleged infringer reasonably related to the enforcement of the PATENT RIGHTS under this Article including but not limited to antitrust counterclaims and claims for recovery of attorney fees.

8.5 Notwithstanding the foregoing, LICENSEE shall not file or continue any suit without LICENSEE (a) having first performed a thorough, diligent investigation of the merits of such suit, including with respect to the validity and enforceability of the PATENT RIGHTS; (b) having reasonable, supportable legal and economic bases for doing so; (c) receiving notice from MICHIGAN that MICHIGAN agrees that LICENSEE's diligence has satisfied MICHIGAN's own legal and business diligence requirements that the suit is reasonable; and (d) jointly addressing the legal representation issues in Section 8.4 with MICHIGAN.

8.6 Each party shall diligently cooperate with the other in litigation proceedings and other activities related to this Article. Except as provided herein, the parties shall jointly control and consult one another with respect to any filed litigation and any counterclaims related thereto, and are generally expected to make joint filings. The parties shall meet and confer in good faith with respect to any action, and shall reasonably consider the other party's input. If there is any disagreement on strategy that is not resolved with the mediation of outside counsel, the parties agree that, so long as lead outside counsel agrees that a position both is not unreasonable and is allowable under court and legal rules, that: (a) LICENSEE shall have the right to control ultimate decisions on strategy matters that are primary infringement issues, and (b) MICHIGAN shall have the right to control ultimate decisions on strategy matters that are primarily validity and inequitable conduct issues. LICENSEE shall make any settlement only with the advice and consent of MICHIGAN.

8.7 If there is litigation to enforce the PATENT RIGHTS and damages are recovered in litigation or settlement thereof, the award shall be applied first to satisfy MICHIGAN's and LICENSEE's reasonable expenses and legal fees therefor. The remaining balance shall be divided equally between LICENSEE and MICHIGAN. (Provided, however, that if any amounts of any type whatsoever are outstanding under this Agreement at the time of such recovery, they shall be paid directly to, or retained by, MICHIGAN from the amounts otherwise payable to LICENSEE under the prior sentence.) For clarity, the damages, expenses, and legal fees are only those that are for the PATENT RIGHTS, but not other patents. The parties hereto agree to negotiate a resolution in good faith should any such damages or recoveries be related to patents other than the PATENT RIGHTS. This provision shall control the division of revenues where a sublicense, covenant not to sue, or assignment of rights is granted as part of a settlement of such lawsuit (including prospective rights).

ARTICLE 9-NO WARRANTIES; LIMITATION ON MICHIGAN'S LIABILITY

9.1 MICHIGAN, including its Regents, fellows, officers, employees and agents, makes no representations or warranties that PATENT RIGHTS are or will be held valid or enforceable, or that the manufacture, importation, use, offer for sale, sale or other distribution of any LICENSED PRODUCTS or LICENSED PROCESSES will not infringe upon any patent or other rights.

9.2 MICHIGAN, INCLUDING ITS REGENTS, FELLOWS, OFFICERS, EMPLOYEES AND AGENTS, MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY LICENSEE OR SUBLICENSEES OF LICENSED PRODUCTS OR LICENSED PROCESSES.

9.3 LICENSEE AND SUBLICENSEES ASSUME THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS AND LICENSED PROCESSES. In no event shall MICHIGAN, including its Regents, fellows, officers, employees and agents, be responsible or liable for any direct, indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to LICENSED PRODUCTS or LICENSED PROCESSES, to LICENSEE, SUBLICENSEES or any other individual or entity regardless of legal or equitable theory. The above limitations on liability apply even though MICHIGAN, its Regents, fellows, officers, employees or agents may have been advised of the possibility of such damage.

9.4 LICENSEE shall not, and shall require that its SUBLICENSEES do not, make any statements, representations or warranties whatsoever to any person or entity, or accept any liabilities or responsibilities whatsoever from any person or entity that are inconsistent with any disclaimer or limitation included in this Article 9.

ARTICLE 10 - INDEMNITY; INSURANCE

10.1 LICENSEE shall defend, indemnify and hold harmless and shall require SUBLICENSEES to defend, indemnify and hold harmless MICHIGAN, including its Regents, fellows, officers, employees, students, and agents, for and against any and all claims, demands, damages, losses, and expenses of any nature (including attorneys' fees and other litigation expenses), resulting from, but not limited to, death, personal injury, illness, property damage, economic loss or products liability arising from or in connection with, any of the following: (1) Any manufacture, use, sale or other disposition by LICENSEE, SUBLICENSEES or transferees of LICENSED PRODUCTS or LICENSED PROCESSES; (2) The use by any person of LICENSED PRODUCTS made, used, sold or otherwise distributed by LICENSEE or SUBLICENSEES; and (3) The use or practice by LICENSEE or SUBLICENSEES of any invention or computer software related to the PATENT RIGHTS.

10.2 MICHIGAN is entitled to participate at its option and expense through counsel of its own selection, and may join in any legal actions related to any such claims, demands, damages, losses and expenses under Paragraph 10.1 above. LICENSEE shall not settle any such legal action with an admission of liability of MICHIGAN without MICHIGAN's written approval.

10.3 Prior to any distribution or commercial use of any LICENSED PRODUCT or use of any LICENSED PROCESS by LICENSEE, LICENSEE shall purchase and maintain in effect commercial general liability insurance, including product liability insurance and errors and omissions insurance which shall protect LICENSEE and MICHIGAN with respect the events covered by Paragraph 10.1. Prior to any distribution or use of any LICENSED PRODUCT or use of any LICENSED PROCESS by a SUBLICENSEE, LICENSEE shall require that the SUBLICENSEE purchase and maintain in effect commercial general liability insurance, including product liability insurance and errors and omissions insurance which shall protect LICENSEE, SUBLICENSEE, and MICHIGAN with respect to the events covered by Paragraph 10.1. Each such insurance policy must provide reasonable coverage for all claims with respect to any LICENSED PROCESS used and any LICENSED PRODUCTS manufactured, used, sold, licensed or otherwise distributed by LICENSEE -- or, in the case of a SUBLICENSEE's policy, by said SUBLICENSEE -- and must specify MICHIGAN, including its Regents, fellows, officers and employees, as an additional insured. LICENSEE shall furnish certificate(s) of such insurance to MICHIGAN, upon request.

10.4 In no event shall either party hereunder be liable to the other for any special, indirect, or consequential damages of any kind whatsoever resulting from any breach or default of this Agreement.

ARTICLE 11 -TERM AND TERMINATION

11.1 If LICENSEE ceases to carry on its business, this Agreement shall terminate upon written notice by MICHIGAN attempted to be delivered to the address for notices provided in Article 13.

11.2 If LICENSEE fails to make any payment due to MICHIGAN, upon ten (10) days' written notice by MICHIGAN, this Agreement shall automatically terminate unless MICHIGAN specifically extends such date in writing. Such termination shall not foreclose MICHIGAN from collection of any amounts remaining unpaid or seeking other legal relief.

11.3 Upon any material breach or default of this Agreement by LICENSEE (other than as specifically provided herein, the terms of which shall take precedence over the handling of any other material breach or default under this Paragraph), MICHIGAN has the right to terminate this Agreement effective on thirty (30) days' written notice to LICENSEE. Such termination shall become automatically effective upon expiration of the thirty day period unless LICENSEE cures the material breach or default before the period expires.

11.4 LICENSEE has the right to terminate this Agreement at any time on ninety (90) days' written notice to MICHIGAN if LICENSEE first:

- (a) pays all amounts due MICHIGAN through the effective date of the termination;
- (b) submits a final report of the type described in Paragraph 4.2;
- (c) returns any patent documentation (including that exchanged under Article 7) and any other confidential or trade-secret materials provided to LICENSEE by MICHIGAN in connection with this Agreement, or, with prior approval by MICHIGAN, destroys such materials, and certifies in writing that such materials have all been returned or destroyed;
- (d) suspends its manufacture, use and sale of the LICENSED PROCESS(ES) AND LICENSED PRODUCT(S);
- (e) provides MICHIGAN with all data and know-how developed by LICENSEE in the course of LICENSEE's efforts to develop LICENSED PRODUCTS and LICENSED PROCESSES; MICHIGAN shall have the right to use such data and know-how for any purpose whatsoever, including the right to transfer same to future licensees; and
- (f) provides MICHIGAN access to any regulatory information filed with any U.S. or foreign government agency with respect to LICENSED PRODUCTS and LICENSED PROCESSES.

Upon notice of intent to terminate, MICHIGAN may elect to immediately terminate this Agreement upon written notice.

11.5 Upon any termination of this Agreement, and except as provided herein to the contrary, all rights and obligations of the parties hereunder shall cease, except any previously accrued rights and obligations and further as follows:

- (1) obligations to pay royalties and other sums, or to transfer equity or other consideration, accruing hereunder up to the day of such termination, whether or not this Agreement provides for a number of days before which actual payment is due and such date is after the day of termination;
- (2) MICHIGAN's rights to inspect books and records as described in Article 4, and LICENSEE's obligations to keep such records for the required time;
- (3) any cause of action or claim of LICENSEE or MICHIGAN accrued or to accrue because of any breach or default by the other party hereunder;

(4) the provisions of Articles I, 9, 10, and 14; and

(5) all other terms, provisions, representations, rights and obligations contained in this Agreement that by their sense and context are intended to survive until performance thereof by either or both parties.

11.6 After the license(s) granted herein terminate, if LICENSEE has filed patent applications or obtained patents to any modification or improvement to LICENSED PRODUCTS or LICENSED PROCESSES within the scope of the PATENT RIGHTS, LICENSEE agrees upon request to enter into good faith negotiations with MICHIGAN or MICHIGAN's future licensee(s) for the purpose of granting licensing rights to said modifications or improvements in a timely fashion and under commercially reasonable terms.

11.7 If LICENSEE asserts the invalidity or unenforceability of any claim included in the PATENT RIGHTS, including by way of litigation or administrative proceedings, either directly or through any other party, then MICHIGAN shall have the right to immediately terminate this Agreement upon written notice to LICENSEE.

ARTICLE 12 - REGISTRATION AND RECORDATION

12.1 If the terms of this Agreement, or any assignment or license under this Agreement are or become such as to require that the Agreement or license or any part thereof be registered with or reported to a national or supranational agency, LICENSEE will, at its expense, undertake such registration or report. Prompt notice and appropriate verification of the act of registration or report or any agency ruling resulting from it will be supplied by LICENSEE to MICHIGAN upon request.

12.2 LICENSEE shall also carry out, at its expense, any formal recordation of this Agreement or any license herein granted that the law of any country requires as a prerequisite to enforceability of the Agreement or license in the courts of any such country or for other reasons, and shall promptly furnish to MICHIGAN appropriately verified proof of recordation.

ARTICLE 13 - NOTICES

13.1 Any notice, request, or report required or permitted to be given or made under this Agreement by either party is effective when mailed if sent by recognized overnight carrier, certified or registered mail, or electronic mail followed by confirmation by U.S. mail, to the address set forth below or such other address as such party specifies by written notice given in conformity herewith. Any notice, request, or report not so given is not effective until actually received by the other party.

To MICHIGAN:

The University of Michigan
Innovation Partnerships
1600 Huron Parkway
Building 520 2nd Floor
Ann Arbor, MI 48109
Attn: [***]

To LICENSEE:

Ascentage Pharma Group Corp. Ltd.
Unit B, 17/F., United Centre, 95 Queensway,
Admiralty, Hong Kong
Attn: Dajun Yang, President and CEO

ARTICLE 14 - MISCELLANEOUS PROVISIONS

14.1 This Agreement shall be construed, governed, interpreted and applied according to United States and state of Michigan law, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was granted.

14.2 The parties hereby consent to the jurisdiction of the courts in the state of Michigan over any dispute concerning this Agreement or the relationship between the parties. Should LICENSEE bring any claim, demand or other action against MICHIGAN, its Regents, fellows, officers, employees or agents, arising out of this Agreement or the relationship between the parties, LICENSEE agrees to bring said action only in the Michigan Court of Claims.

14.3 MICHIGAN and LICENSEE agree that this Agreement sets forth their entire understanding concerning the subject matter of this Agreement. The parties may amend this Agreement from time to time, but no modification will be effective unless both MICHIGAN and LICENSEE agree to it in writing.

14.4 If a court of competent jurisdiction finds any term of this Agreement invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

14.5 LICENSEE agrees to mark the LICENSED PRODUCTS sold in the United States with all applicable United States patent numbers. All LICENSED PRODUCTS shipped to or sold in other countries shall be marked to comply with the patent laws and practices of the countries of manufacture, use and sale.

14.6 No waiver by either party of any breach of this Agreement, no matter how long continuing or how often repeated, is a waiver of any subsequent breach thereof, nor is any delay or omission on the part of either party to exercise or insist on any right, power, or privilege hereunder a waiver of such right, power or privilege. In no event shall any waiver be deemed valid unless it is in writing and signed by an authorized representative of each party.

14.7 LICENSEE agrees to refrain from using and to require SUBLICENSEES to refrain from using the name of MICHIGAN in publicity or advertising without the prior written approval of MICHIGAN. Reports in scientific literature and presentations of joint research and development work are not publicity. Notwithstanding this provision, without prior written approval of MICHIGAN, LICENSEE and SUBLICENSEES may state publicly that LICENSED PRODUCTS and PROCESSES were developed by LICENSEE based upon an invention(s) developed at the University of Michigan and/or that the PATENT RIGHTS were licensed from the University of Michigan.

14.8 LICENSEE agrees to comply with all applicable laws and regulations. In particular, LICENSEE understands and acknowledges that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations prohibit or require a license for the export of certain types of technical data to certain specified countries. LICENSEE agrees to comply with all United States laws and regulations controlling the export of commodities and technical data, to be solely responsible for any violation of such laws and regulations by LICENSEE or its SUBLICENSEES, and to defend, indemnify and hold harmless MICHIGAN and its Regents, fellows, officers, employees and agents if any legal action of any nature results from the violation.

14.9 The relationship between the parties is that of independent contractor and contractee. Neither party is an agent of the other in connection with the exercise of any rights hereunder, and neither has any right or authority to assume or create any obligation or responsibility on behalf of the other.

14.10 LICENSEE may not assign this Agreement without the prior written consent of MICHIGAN and shall not pledge any of the license rights granted in this Agreement as security for any creditor. Any attempted pledge of any of the rights under this Agreement or assignment of this Agreement without the prior consent of MICHIGAN will be void from the beginning. No assignment by LICENSEE will be effective until the intended assignee agrees in writing to accept all of the terms and conditions of this Agreement, and such writing is provided to MICHIGAN. Notwithstanding, LICENSEE may, without MICHIGAN's consent, assign its rights under this Agreement to a purchaser of all or substantially all of LICENSEE's business relating to the subject matter of this Agreement, so long as such assignee provides a statement in writing to MICHIGAN that it agrees to accept all the terms and conditions of this Agreement in the place of LICENSEE.

14.11 If during the term of this Agreement, LICENSEE makes or attempts to make an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy or insolvency are instituted on behalf of or against LICENSEE, or if a receiver or trustee is appointed for the property of LICENSEE, this Agreement shall automatically terminate. LICENSEE shall notify MICHIGAN of any such event mentioned in this Paragraph as soon as reasonably practicable, and in any event within five (5) days after any such event.

ARTICLE 15 - CONFLICT OF INTEREST MANAGEMENT

15.1 This Agreement and the licenses granted hereunder are subject to approval by a two- thirds majority vote of the Regents of the University of Michigan.

15.2 Unless MICHIGAN provides appropriate formal approvals, continuing development of LICENSED PRODUCTS and LICENSED PROCESSES will take place without the use of MICHIGAN funds, facilities, or other resources of or funds administered by MICHIGAN.

15.3 LICENSEE shall cooperate with MICHIGAN in developing and implementing appropriate plans for management of potential conflicts of interest and conflicts of commitment of MICHIGAN employees.

IN WIINESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

For:	LICENSEE	For:	The Regents of the University of Michigan
By:	<u>/S/ Dajun Yang, M.D., Ph.D.</u> (authorized representative)	By:	<u>/S/ Bryce Pilz</u>
Name:	_____	Name:	_____
Title:	Chairman & CEO	Title:	_____
Date:	_____	Date:	_____

APPENDIX A TO LICENSE
AGREEMENT

EQUITY TRANSFER
AGREEMENT BETWEEN
[NAME OF LICENSEE]
AND THE REGENTS OF THE UNIVERSITY OF MICHIGAN

[**]

CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN REDACTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.**

LICENSE AGREEMENT

This License Agreement (“Agreement”) is effective as of August 12, 2025 (the “Effective Date”), between Ascentage Pharma Group (“LICENSEE”) having the address in Article 13 below, and the Regents of the University of Michigan, a constitutional corporation of the state of Michigan (“MICHIGAN”). MICHIGAN and the LICENSEE are collectively referred to herein as the “PARTIES”.

WHEREAS, the LICENSEE wishes to acquire rights to PATENT RIGHTS directed to inventions listed in Exhibit A, including the right to provide such licenses to third parties;

WHEREAS, the PARTIES discussed differing structures for the payment of royalties hereunder, however for the convenience of the parties in measuring the value of the licenses granted herein, the PARTIES have negotiated the combination of fees and percentage of net sales (including the royalty base and rate provided below);

NOW THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the PARTIES hereby agree as follows:

ARTICLE 1 - DEFINITIONS

1.1 “CHINA” means mainland China, Hong Kong, Macau and Taiwan.

1.2 “FIELD OF USE” means all fields.

1.3 “FIRST COMMERCIAL SALE” the first invoiced sale for monetary value for use or consumption by the end user of such LICENSED PRODUCT after regulatory approval for such LICENSED PRODUCT has been obtained in the TERRITORY and where the sale results in a recordable NET SALES in accordance with applicable accounting standard of LICENSEE, provided that (a) any indigent patient, clinical trial or any compassionate or named patient, charitable or humanitarian programs shall not be considered a FIRST COMMERCIAL SALE and (b) sale of a LICENSED PRODUCT under this Agreement by or on behalf of LICENSEE or its Affiliates or its or their sublicensees (“LICENSEE PARTY” to another LICENSEE PARTY shall not be considered a FIRST COMMERCIAL SALE unless such LICENSEE Party is the end user of such LICENSED PRODUCT and such sale results in a recordable NET SALES..

1.4 “GROSS SUBLICENSING REVENUES” means all revenue or consideration due to LICENSEE from a SUBLICENSEE in consideration for rights under or relating to the PATENT RIGHTS (including, but not limited to, license issue fees, maintenance or annual minimum fees, amounts based on product sales, milestone payments, other royalties) whether received in cash or equity. GROSS SUBLICENSING REVENUES shall not include amounts that a SUBLICENSEE pays to LICENSEE that are specifically identified for research and development, any indigent patient, or any compassionate or named patient, charitable or humanitarian programs or where LICENSEE is the end user of such LICENSED PRODUCT and such sale is not a recordable NET SALES.

1.5 “LICENSED PROCESS(ES)” means any process or method that, but for this Agreement, comprises an infringement of (including contributory or inducement), or is covered by, an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS or uses a LICENSED PRODUCT.

1.6 “LICENSED PRODUCT(S)” means any product that: (a) but for this Agreement comprises an infringement of (including contributory or inducement), or is covered by, an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS in the country in which any such product or product part is made, used, imported, offered for sale or sold; or (b) is manufactured by using a LICENSED PROCESS or is employed to practice a LICENSED PROCESS; or (c) is not a “LICENSED PRODUCT” under subparagraph (a) or (b) of this Paragraph 1.6, but is covered by an issued, but expired, claim in PATENT RIGHTS.

1.7 “NCE” means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act as defined in 21 CFR 314.108.

1.8 “NET SALES” means the amount billed or invoiced, and if any amount is not billed or invoiced, the amounts received, on sales, rental or lease, however characterized, by LICENSEE of LICENSED PRODUCTS and uses or licenses of LICENSED PROCESSES, less the following deductions (but only to the extent such sums are otherwise included in NET SALES and are not obtained in view of other consideration received by LICENSEE):

- (a) cash discounts actually granted to customers in such invoices for sales or lease of LICENSED PRODUCTS, but only in amounts customary in the trade;
- (b) sales, tariff duties and/or use taxes separately stated in such bills or invoices with reference to particular sales and actually paid by LICENSEE to a governmental unit;
- (c) actual freight expenses between LICENSEE and customers, to the extent such expenses are not charged to or reimbursed by customers; or
- (d) amounts actually refunded or credited on returns.

Where LICENSEE receives any consideration other than cash for such transactions, fair market cash value for such consideration, to be agreed upon by the parties hereto, shall be included in NET SALES.

1.9 "PATENT RIGHTS" means MICHIGAN'S legal rights under the patent laws of the United States or relevant foreign countries for all of the following:

(a) the following United States and foreign patent(s) and/or patent application(s) as listed in Exhibit A, and divisionals, continuations (except continuations-in-part), and foreign counterparts of the same:

and

United States and foreign patent(s) and/or patent application(s) (and divisionals, continuations, (except continuations-in-part), and foreign counterparts (including, for the sake of clarity, all foreign national cases claiming priority to the identified PCT applications of the same) which are directed to inventions disclosed to the MICHIGAN Innovation Partnerships and specifically described and enabled in the invention reports of Innovation Partnerships as listed in Exhibit A;

(b) United States and foreign patents issued from the applications listed in subparagraph 1.7(a) above, including any reissued or reexamined patents based upon the same.

1.10 ROYALTY PERIOD(S)" means the six-month periods ending on the last days of June and December each year.

1.11 "ROYALTY TERM" means until the later of (a) expiration of the last to expire of the PATENT RIGHTS; or (b) the tenth (10th) anniversary of the FIRST COMMERCIAL SALE of a LICENSED PRODUCT unless sooner terminated as provided in another specific article of this Agreement.

1.12 "SUBLICENSEE(S)" means any person or entity sublicensed, or granted an option for a sublicense, by LICENSEE under this Agreement.

1.13 "TERRITORY" means worldwide.

ARTICLE 2 - GRANT OF LICENSE

2.1 MICHIGAN hereby grants to LICENSEE an exclusive license under the PATENT RIGHTS, with the right to grant sublicenses, both subject to the terms and conditions of this Agreement, in the FIELD OF USE and the TERRITORY to make, have made, import, use, market, offer for sale and sell LICENSED PRODUCTS and to practice LICENSED PROCESSES.

2.2 Without limiting any other rights it may have, MICHIGAN specifically reserves the right to practice the PATENT RIGHTS for research, public service, internal (including clinical) and/or educational purposes, and the right to grant the same limited rights to other non-profit research institutions.

2.3 LICENSEE agrees that LICENSED PRODUCTS used, leased or sold in the United States shall be manufactured substantially in the United States.

2.4 The licenses granted in this Agreement are subject to any rights required to be granted under prior research or sponsorship agreements, or retained by the U.S. government, for example in accordance with Chapter 18 or Title 35 of U.S.C. 200-212 and the regulations thereunder (37 CFR Part 401), when applicable. LICENSEE agrees to comply in all respects, and shall provide MICHIGAN with all reasonably requested information and cooperation for MICHIGAN to comply with applicable provisions of the same and any requirements of any contracts between MICHIGAN and any agency of the U.S. government that provided funding for the subject matter covered by the PATENT RIGHTS.

ARTICLE 3 - CONSIDERATION

3.1 LICENSEE shall pay royalties to MICHIGAN as follows:

- (a) Upfront payment of [***] within 30 days of the EFFECTIVE DATE.
- (b) Running Royalties shall be paid according to the following:

Royalty rate on Total Annual NET SALES of LICENSED PRODUCTS on each NCE in CHINA

Annual NET SALES up to [***]	[***]
Annual NET SALES of [***]	[***]
Annual NET SALES over [***]	[***]

Royalty rate on Total Annual NET SALES of LICENSED PRODUCTS on each NCE in all other territories:

Annual NET SALES up to [***]	[***]
Annual NET SALES of [***]	[***]
Annual NET SALES of [***]	[***]
Annual NET SALES over [***]	[***]

For NET SALES for LICENSED PRODUCTS under Paragraph 1.6 (a) or (b), the above royalty rates shall apply. For NET SALES for LICENSED PRODUCTS only under Paragraph 1.6 (c), royalty rates shall be [***] of the above rates.

LICENSEE shall pay Royalties to MICHIGAN during the entire Royalty Term, on a LICENSED PRODUCT-by-LICENSED PRODUCT and country-by-country basis and this provision shall survive any termination of this Agreement.

If LICENSEE makes any NET SALES to any party affiliated with LICENSEE, or in any way directly or indirectly related to or under the common control with LICENSEE, at a price less than the regular price charged to other parties, the Royalties payable to MICHIGAN shall be only apply if those sales are booked at NET SALES by LICENSEE and the Royalty shall be computed on the basis of the price paid by commercial payors.

(c) LICENSEE shall pay the following percentage of GROSS SUBLICENSING REVENUES to MICHIGAN.

- (1) [***] if the sublicense agreement is signed before the FDA, or foreign equivalent, approves the LICENSEE or SUBLICENSEE's IND on a LICENSED PRODUCT included in such sublicense agreement;
- (2) [***] if the sublicense agreement is signed after IND but before dosing the first patient in a Phase II clinical trial conducted by LICENSEE or SUBLICENSEE on a LICENSED PRODUCT included in such sublicense agreement; and
- (3) [***] if the sublicense agreement is signed after dosing the first patient in a Phase II clinical trial conducted by LICENSEE or SUBLICENSEE on a LICENSED PRODUCT included in such sublicense agreement.

In the event that GROSS SUBLICENSING REVENUES includes non-cash consideration (i.e., that LICENSEE enters into a sublicense in which a SUBLICENSEE is to pay LICENSEE consideration other than cash), MICHIGAN shall receive its percentage according to the following. In each such instance, LICENSEE shall direct and require SUBLICENSEE to directly transfer to MICHIGAN its share of the total non-cash consideration to be otherwise transferred to LICENSEE within ten (10) days after said SUBLICENSEE transfers said non-cash consideration to LICENSEE. For example, if a SUBLICENSEE agrees to provide consideration in the form of stock in one or more tranches, LICENSEE shall direct and require SUBLICENSEE to directly transfer to MICHIGAN those number of shares of stock representing the appropriate percentage above by said deadline. LICENSEE shall make such transfer pursuant to and subject in substance to the terms of the form of Stock Transfer Agreement attached hereto as Appendix A (the "EQUITY TRANSFER AGREEMENT").

(d) LICENSEE shall pay to MICHIGAN minimum annual royalties ("Annual Fee"). This Annual Fee is accrued on June 30 of the years specified below, and is payable with the semi-annual report for the ROYALTY PERIOD in which the Annual Fee accrues. This Annual Fee is non-creditable and non-refundable. The Annual Fees are:

- (i) For 2025-2027: [***];
- (ii) For 2028-2033: [***];
- (iii) Beginning the year of FIRST COMMERCIAL SALE in [***] or 2034, whichever is earlier: [***]; and

(e) LICENSEE shall pay milestone payments as follows:

- (i) [***] upon enrollment of the [***] patient of the first [***] safety trial for each [***] with a distinct target;
- (ii) [***] upon enrollment of the [***] patient of the first [***] clinical trial for each [***] with a distinct target;
- (iii) [***] upon enrollment of the [***] patient of the first [***] clinical trial for each [***] with a distinct target;
- (iv) [***] upon FIRST COMMERCIAL SALE in the US and for each [***] with a distinct target, and [***] upon FIRST COMMERCIAL SALE for such [***] in each of the [***];

(v) [***] upon first time achieving NET SALES in a calendar year over [***] for each [***] with a distinct target; and

(vi) [***] upon first time achieving NET SALES in a calendar year over [***] for each [***] with a distinct target.

Milestone payments are non-refundable and non-creditable against future royalties.

3.2 LICENSEE shall be responsible for the payment of all taxes, duties, levies, and other charges imposed by any taxing authority with respect to the royalties payable to MICHIGAN under this agreement. Should LICENSEE be required under any law or regulation of any government entity or authority to withhold or deduct any portion of the payments on royalties due to MICHIGAN, then the sum payable to MICHIGAN shall be increased by the amount necessary to yield to MICHIGAN an amount equal to the sum it would have received had no withholdings or deductions been made. MICHIGAN shall cooperate reasonably with LICENSEE in the event LICENSEE elects to assert, at its own expense, MICHIGAN's exemption from any such tax or deduction.

3.3 LICENSEE is not obligated to pay multiple Royalties if any LICENSED PRODUCT or LICENSED PROCESS is covered by more than one claim of PATENT RIGHTS or the same LICENSED PRODUCT is covered by claims in two or more countries.

3.4 Royalty payments shall be made to "The Regents of the University of Michigan" in United States dollars. Payments drawn directly on a U.S. bank may be made by either check to the address in Article 13 or by wire transfer. Any payment drawn on a foreign bank or foreign branch of a U.S. bank shall be made only by wire transfer. Wire transfers shall be made in accordance with the following or any other instructions as may be specified by [***]. In computing Royalties, LICENSEE shall convert any revenues it receives in foreign currency into its equivalent in United States dollars at the most recent exchange rate published in the Wall Street Journal on the last business day of the ROYALTY PERIOD during which such payments are received by LICENSEE, or at such other exchange rate as the parties may agree to in writing.

3.5 Royalty payments shall be made on a semi-annual basis with submission of the reports required by Article 4. All amounts due under this Agreement, including amounts due for the payment of patent expenses, shall, if overdue, be subject to a charge of interest compounded monthly until payment, at a per annum rate of five percent (5%) above the prime rate in effect at the JP Morgan Chase Bank, N.A. or its successor bank on the due date (or at the highest allowed rate if a lower rate is required by law) or \$250, whichever is greater. The payment of such interest shall not foreclose MICHIGAN from exercising any other rights it may have resulting from any late payment. LICENSEE shall reimburse MICHIGAN for the costs, including reasonable attorney fees, for expenses paid in order to collect any amounts overdue more than 120 days.

ARTICLE 4- REPORTS

4.1 Until the FIRST COMMERCIAL SALE, LICENSEE shall provide to MICHIGAN a written annual report on or before July 30 of each year. The annual report shall include reports of progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the preceding twelve (12) months, and plans for the coming year. LICENSEE also shall report to MICHIGAN the date of first sale or lease of LICENSED PRODUCTS (or results of LICENSED PROCESSES) in each country within thirty (30) days of occurrence.

4.2 After the FIRST COMMERCIAL SALE, LICENSEE shall provide semi-annual reports to MICHIGAN. By each July 30 and January 31 (i.e., within one month after each ROYALTY PERIOD closes, including the close of the ROYALTY PERIOD immediately following any termination of this Agreement), LICENSEE shall report to MICHIGAN for that ROYALTY PERIOD:

- (a) number of LICENSED PRODUCTS sold, leased, or distributed, however characterized, by LICENSEE and each SUBLICENSEE.
- (b) NET SALES, excluding the deductions provided therefor, of LICENSED PRODUCTS sold, distributed, used, rented, leased, or licensed, however characterized, by LICENSEE and all SUBLICENSEES.
- (c) accounting for all LICENSED PROCESSES used, sold, or licensed, however characterized, by LICENSEE and all SUBLICENSEES included in NET SALES, excluding the deductions thereof.
- (d) deductions applicable as provided in the definition for NET SALES above.
- (e) amounts due on payments from SUBLICENSEE under Paragraph 3.1 above, including supporting documentation, including but not limited to any non-cash consideration owed by SUBLICENSEE to LICENSEE.
- (f) foreign currency conversion rate and calculations (if applicable) and total royalties due.
- (g) names, addresses, and U.S.P.T.O. Entity Status (as discussed in Paragraph 4.5) of all SUBLICENSEES having a sublicense or option therefor any time during the particular ROYALTY PERIOD.
- (h) for each sublicense or amendment thereto completed in the particular ROYALTY PERIOD (including agreements under which LICENSEE will have LICENSED PRODUCTS made by a third party), the date of each agreement and amendment, the territory of the sublicense, the scope of the sublicense, and the nature, timing and amounts of all fees and royalties to be paid thereunder.
- (i) any milestone (under Article 3 or Article 5) that has been achieved, and any milestone that was due during the ROYALTY PERIOD but not achieved, specifying each milestone and whether or not it was achieved.

LICENSEE shall include the amount of all payments due, and the various calculations used to arrive at those amounts, including the quantity, description (nomenclature and type designation as described in Paragraph 4.3 below), country of manufacture and country of sale or use of LICENSED PRODUCTS and LICENSED PROCESSES. LICENSEE shall direct its authorized representative to certify that reports required hereunder are correct to the best of LICENSEE's knowledge and information. Failure to provide reports as required under this Article 4 shall be a material breach of this Agreement.

If no payment is due, LICENSEE shall so report to MICHIGAN that no payment is due.

4.3 LICENSEE shall promptly establish and consistently employ a system of specific nomenclature and type designations for LICENSED PRODUCTS and LICENSED PROCESSES to permit identification and segregation of various types where necessary. LICENSEE shall consistently employ, and shall require SUBLICENSEES to consistently employ, the system when rendering invoices thereon and shall inform MICHIGAN, or its auditors, when requested, as to the details concerning such nomenclature system, all additions thereto and changes therein.

4.4 LICENSEE shall keep, and shall require SUBLICENSEES to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. LICENSEE shall, and it shall require all SUBLICENSEES and those making LICENSED PRODUCTS, to: (a) open such records for inspection upon reasonable notice during business hours, and no more than once per year, by either MICHIGAN auditor(s) or an independent certified accountant selected by MICHIGAN, for the purpose of verifying the amount of payments due; and (b) retain such records for six (6) years from date of origination.

The terms of this Article shall survive any termination of this Agreement. MICHIGAN is responsible for all expenses of such inspection, except that if any inspection reveals an underpayment greater than five percent (5%) of royalties due MICHIGAN, then LICENSEE shall pay all expenses of that inspection and the amount of the underpayment and interest to MICHIGAN within twenty-one (21) days of written notice thereof. LICENSEE shall also reimburse MICHIGAN for reasonable expenses required to collect the amount underpaid.

4.5 So that MICHIGAN may pay the proper U.S. Patent and Trademark Office fees relating to the PATENT RIGHTS, if LICENSEE, any company related to LICENSEE or SUBLICENSEE (including optionees) does not qualify as a "Small Entity" under U.S. patent laws, LICENSEE shall notify MICHIGAN immediately. The parties understand that the changes to LICENSEE's, SUBLICENSEE's, or optionees' businesses that might affect entity status include: acquisitions, mergers, hiring of a total of more than 500 total employees, sublicense agreements, and sublicense options.

4.6 Affordable Access Plan. Within three (3) months of receiving FDA (or its foreign equivalent's) approval of a LICENSED PRODUCT, LICENSEE will provide MICHIGAN with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), LICENSEE agrees to discuss such reasoning with MICHIGAN in good faith within one (1) month thereafter ("Initial Discussion") and, if following such Initial Discussion MICHIGAN concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to MICHIGAN within three (3) months of such Initial Discussion. The "Affordable Access Plan" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in the U.S., as defined by the Department of Health and Human Services, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that MICHIGAN can make available to third parties: (a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory"); (b) LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations; and (c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S. Within thirty (30) days of MICHIGAN's request (but no more often than once annually), LICENSEE agrees to confer with MICHIGAN to review LICENSEE'S progress, and to consider in good faith any modifications suggested by MICHIGAN, with respect to its Affordable Access Plan ("Progress Discussions").

ARTICLE 5 - DILIGENCE

5.1 LICENSEE shall use commercially reasonable efforts to bring a full scope of LICENSED PRODUCTS to market or one or more LICENSED PROCESSES to commercial use through a thorough, vigorous and diligent program for exploiting the PATENT RIGHTS and to continue active, diligent marketing efforts throughout the life of this Agreement. LICENSEE has the responsibility to do all that is necessary to obtain and retain any governmental approvals to manufacture and/or sell LICENSED PRODUCTS and/or use LICENSED PROCESSES for all relevant activities of LICENSEE and SUBLICENSEES.

5.2 With respect to each Invention Report in Exhibit A and/or in any future amendment to this Agreement, LICENSEE agrees to reach the following commercialization and research and development milestones with respect to LICENSED PRODUCTS that are covered by PATENT RIGHTS (together the "MILESTONES") by the following dates:

1. Nominate clinical development lead compound [***] including non-GMP scale-up production, pre-formulation, non-GLP preclinical toxicity and pharmacokinetic studies of the lead compounds completed for such selection within thirty-six (36) months after the date the of the PATENT RIGHTS covering such [***] is added into this Agreement.
2. IND filing with US FDA or equivalent regulatory agency of foreign countries such as NMPA in CHINA for each NCE project, including GMP scale-up production and GLP toxicology studies of the lead compounds completed for such selection with eighteen (18) months of selection of the clinical development lead compounds.
3. Initiate [***] trials for each [***] within twelve (12) months of [***] filing with appropriate regulatory agency.
4. Initiate [***] clinical trials for each [***] within twelve (12) months of successful completion of [***] trials.
5. Initiate [***] clinical trials for each [***] with twelve (12) months of successful completion of [***].

5.3 LICENSEE must achieve each MILESTONE on or before the deadline dates indicated and MICHIGAN shall have the sole discretion to determine the validity of a MILESTONE being reached. LICENSEE shall notify MICHIGAN within ten (10) days after each such deadline as to whether or not such MILESTONE was met. If LICENSEE fails to meet any MILESTONE under this Article by the date of any MILESTONE deadline, LICENSEE will be deemed to be in material breach of this Agreement, and MICHIGAN may terminate the Agreement effective on thirty (30) days' notice, unless LICENSEE achieves the MILESTONE within this thirty day period. Notwithstanding, MICHIGAN may terminate this Agreement immediately if LICENSEE fails to achieve a MILESTONE by the indicated date and does not provide the notice to MICHIGAN referred to above.

ARTICLE 6 - SUBLICENSING

6.1 LICENSEE shall notify MICHIGAN in writing of every sublicense agreement and each amendment thereto within thirty (30) days after their execution, and indicate the name of the SUBLICENSEE and its number of employees, the territory of the sublicense, the scope of the sublicense, and the nature, timing and amounts of all fees and royalties to be paid thereunder. Upon request, LICENSEE shall provide MICHIGAN with a copy of sublicense agreements.

6.2 LICENSEE shall not receive from SUBLICENSEES anything of value other than cash payments in consideration for any sublicense under this Agreement, without the express prior written permission of MICHIGAN.

6.3 Each sublicense granted by LICENSEE under this Agreement shall provide for its termination upon termination of this Agreement. Each sublicense shall terminate upon termination of this Agreement unless LICENSEE has previously assigned its rights under the sublicense to MICHIGAN and MICHIGAN has agreed at its sole discretion in writing to such assignment.

6.4 LICENSEE shall require that all sublicenses:

- (1) be consistent with the terms and conditions of this Agreement;
- (2) contain the SUBLICENSEE'S acknowledgment of the disclaimer of warranty and limitation on MICHIGAN's liability, as provided by Article 9 below; and
- (3) contain provisions under which the SUBLICENSEE accepts duties at least equivalent to those accepted by the LICENSEE in the following Paragraphs: 4.4 (duty to keep records); 4.5 (duty regarding Patent Office fees); 9.4 (duty to avoid improper representations or responsibilities); 10.1 (duty to defend, hold harmless, and indemnify MICHIGAN); 10.3 (duty to maintain insurance); 14.5 (duty to properly mark LICENSED PRODUCTS with patent notices); 14.7 (duty to restrict the use of MICHIGAN's name); 14.8 (duty to control exports).

ARTICLE 7 -PATENT APPLICATIONS AND MAINTENANCE

7.1 MICHIGAN has the right to control all aspects of filing, prosecuting, and maintaining all of the patents and patent applications that form the basis for the PATENT RIGHTS, interferences, and disputes (including litigation) regarding inventorship. LICENSEE shall fully cooperate in such activities.

7.2 MICHIGAN shall notify LICENSEE of all information received by MICHIGAN relating to the filing, prosecution and maintenance of the patents and patent applications which form the basis of the PATENT RIGHTS, and shall make reasonable efforts to allow LICENSEE to review, comment, and advise upon such information. LICENSEE agrees to hold such information confidential and to use the information provided by MICHIGAN only for the purpose of advancing MICHIGAN's PATENT RIGHTS.

7.3 LICENSEE shall reimburse MICHIGAN for all fees and costs relating to the activities described in this Article. Such reimbursement shall be made within thirty (30) days of receipt of MICHIGAN's invoice and shall be subject to the interest and other requirements specified in Paragraph 3.5 above.

ARTICLE 8 – ENFORCEMENT

8.1 Each party shall promptly advise the other in writing of any acts of potential infringement of the PATENT RIGHTS by a third party (the "Notice"), and provide any evidence thereof at the request of the other party. After the Notice, LICENSEE shall use diligent efforts to eliminate such infringement without litigation, including, if reasonable, by attempting communications with such third party after consulting MICHIGAN. MICHIGAN's Innovation Partnerships shall provide reasonable assistance to advance such efforts. Beginning at the time of the Notice, each party shall reasonably consider and discuss entering into a common interest agreement and/or joint legal representation.

8.2 To the extent the described activities do not result in the elimination of such infringement, LICENSEE shall share with MICHIGAN, subject to appropriate confidentiality and joint privilege/common interest agreement(s) to be negotiated in good faith between the parties, the complete results of the LICENSEE's diligence related to the potential infringement identified above (including, but not limited to, a detailed infringement analysis), as may be updated from time to time. The parties shall jointly identify a strategy with respect to addressing the infringement.

8.3 Subject to the other terms in this Article and LICENSEE being in compliance with the other terms of this Agreement (unless otherwise agreed to by MICHIGAN), LICENSEE has the right to direct that the parties enforce the PATENT RIGHTS against infringement by other parties within the TERRITORY and the FIELD OF USE, including those prior to the EFFECTIVE DATE. LICENSEE's right begins upon the earlier of (a) the FIRST COMMERCIAL SALE or (b) LICENSEE making a bona fide Investigational Device Exemption or Investigational New Drug Application (or equivalent) filing with the United States Food and Drug Administration or equivalent agency in Europe, China, or Japan (to the extent included within the TERRITORY). If MICHIGAN is a necessary or indispensable party under applicable law in order for a given reasonable lawsuit to enforce the PATENT RIGHTS within the LICENSED TERRITORY and FIELD OF USE to proceed, MICHIGAN shall join in such lawsuit, subject to the other terms of this Article. Each party may grant or delegate to third parties the right to enforce hereunder, and within the LICENSED TERRITORY and FIELD OF USE, only with the express written permission of the other party.

8.4 With respect to the filing and prosecution of infringement lawsuits, the parties agree to negotiate in good faith to jointly select lead counsel (to be a large, nationally recognized litigation firm) and local counsel (if lead counsel does not have an office in the location of the suit) that would represent both parties in the infringement lawsuit, each counsel to have demonstrated significant experience in the applicable legal work. LICENSEE shall reimburse MICHIGAN for out-of-pocket expenses incurred in connection with MICHIGAN's activities under this Article, including but not limited to outside counsel expenses incurred prior to, during, and in the settlement of such litigation, within 30 days after receiving an invoice from MICHIGAN thereof. Upon the determination to file suit or retain counsel in accordance with this Article, or at any other time requested by a party, the parties shall negotiate in good faith a written agreement consistent with the foregoing and this Agreement specifying any further reasonable details. LICENSEE shall indemnify and hold harmless MICHIGAN with respect to any claims asserted by an alleged infringer reasonably related to the enforcement of the PATENT RIGHTS under this Article including but not limited to antitrust counterclaims and claims for recovery of attorney fees.

8.5 Notwithstanding the foregoing, LICENSEE shall not file or continue any suit without LICENSEE (a) having first performed a thorough, diligent investigation of the merits of such suit, including with respect to the validity and enforceability of the PATENT RIGHTS; (b) having reasonable, supportable legal and economic bases for doing so; (c) receiving notice from MICHIGAN that MICHIGAN agrees that LICENSEE's diligence has satisfied MICHIGAN's own legal and business diligence requirements that the suit is reasonable; and (d) jointly addressing the legal representation issues in Section 8.4 with MICHIGAN.

8.6 Each party shall diligently cooperate with the other in litigation proceedings and other activities related to this Article. Except as provided herein, the parties shall jointly control and consult one another with respect to any filed litigation and any counterclaims related thereto, and are generally expected to make joint filings. The parties shall meet and confer in good faith with respect to any action, and shall reasonably consider the other party's input. If there is any disagreement on strategy that is not resolved with the mediation of outside counsel, the parties agree that, so long as lead outside counsel agrees that a position both is not unreasonable and is allowable under court and legal rules, that: (a) LICENSEE shall have the right to control ultimate decisions on strategy matters that are primary infringement issues, and (b) MICHIGAN shall have the right to control ultimate decisions on strategy matters that are primarily validity and inequitable conduct issues. LICENSEE shall make any settlement only with the advice and consent of MICHIGAN.

8.7 If there is litigation to enforce the PATENT RIGHTS and damages are recovered in litigation or settlement thereof, the award shall be applied first to satisfy MICHIGAN's and LICENSEE's reasonable expenses and legal fees thereof. The remaining balance shall be divided equally between LICENSEE and MICHIGAN. (Provided, however, that if any amounts of any type whatsoever are outstanding under this Agreement at the time of such recovery, they shall be paid directly to, or retained by, MICHIGAN from the amounts otherwise payable to LICENSEE under the prior sentence.) For clarity, the damages, expenses, and legal fees are only those that are for the PATENT RIGHTS, but not other patents. The parties hereto agree to negotiate a resolution in good faith should any such damages or recoveries be related to patents other than the PATENT RIGHTS. This provision shall control the division of revenues where a sublicense, covenant not to sue, or assignment of rights is granted as part of a settlement of such lawsuit (including prospective rights).

ARTICLE 9 - NO WARRANTIES; LIMITATION ON MICHIGAN'S LIABILITY

9.1 MICHIGAN, including its Regents, fellows, officers, employees and agents, makes no representations or warranties that PATENT RIGHTS are or will be held valid or enforceable, or that the manufacture, importation, use, offer for sale, sale or other distribution of any LICENSED PRODUCTS or LICENSED PROCESSES will not infringe upon any patent or other rights.

9.2 **MICHIGAN, INCLUDING ITS REGENTS, FELLOWS, OFFICERS, EMPLOYEES AND AGENTS, MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITIES WHATEVER WITH RESPECT TO DESIGN, DEVELOPMENT, MANUFACTURE, USE, SALE OR OTHER DISPOSITION BY LICENSEE OR SUBLICENSEES OF LICENSED PRODUCTS OR LICENSED PROCESSES.**

9.3 **LICENSEE AND SUBLICENSEES ASSUME THE ENTIRE RISK AS TO PERFORMANCE OF LICENSED PRODUCTS AND LICENSED PROCESSES.** In no event shall MICHIGAN, including its Regents, fellows, officers, employees and agents, be responsible or liable for any direct, indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage with respect to LICENSED PRODUCTS or LICENSED PROCESSES, to LICENSEE, SUBLICENSEES or any other individual or entity regardless of legal or equitable theory. The above limitations on liability apply even though MICHIGAN, its Regents, fellows, officers, employees or agents may have been advised of the possibility of such damage.

9.4 LICENSEE shall not, and shall require that its SUBLICENSEES do not, make any statements, representations or warranties whatsoever to any person or entity, or accept any liabilities or responsibilities whatsoever from any person or entity that are inconsistent with any disclaimer or limitation included in this Article 9.

ARTICLE 10 - INDEMNITY; INSURANCE

10.1 LICENSEE shall defend, indemnify and hold harmless and shall require SUBLICENSEES to defend, indemnify and hold harmless MICHIGAN, including its Regents, fellows, officers, employees, students, and agents, for and against any and all claims, demands, damages, losses, and expenses of any nature (including attorneys' fees and other litigation expenses), resulting from, but not limited to, death, personal injury, illness, property damage, economic loss or products liability arising from or in connection with, any of the following: (1) Any manufacture, use, sale or other disposition by LICENSEE, SUBLICENSEES or transferees of LICENSED PRODUCTS or LICENSED PROCESSES; (2) The use by any person of LICENSED PRODUCTS made, used, sold or otherwise distributed by LICENSEE or SUBLICENSEES; and (3) The use or practice by LICENSEE or SUBLICENSEES of any invention or computer software related to the PATENT RIGHTS.

10.2 MICHIGAN is entitled to participate at its option and expense through counsel of its own selection, and may join in any legal actions related to any such claims, demands, damages, losses and expenses under Paragraph 10.1 above. LICENSEE shall not settle any such legal action with an admission of liability of MICHIGAN without MICHIGAN's written approval.

10.3 Prior to any distribution or commercial use of any LICENSED PRODUCT or use of any LICENSED PROCESS by LICENSEE, LICENSEE shall purchase and maintain in effect commercial general liability insurance, including product liability insurance and errors and omissions insurance which shall protect LICENSEE and MICHIGAN with respect the events covered by Paragraph 10.1. Prior to any distribution or use of any LICENSED PRODUCT or use of any LICENSED PROCESS by a SUBLICENSEE, LICENSEE shall require that the SUBLICENSEE purchase and maintain in effect commercial general liability insurance, including product liability insurance and errors and omissions insurance which shall protect LICENSEE, SUBLICENSEE, and MICHIGAN with respect to the events covered by Paragraph 10.1. Each such insurance policy must provide reasonable coverage for all claims with respect to any LICENSED PROCESS used and any LICENSED PRODUCTS manufactured, used, sold, licensed or otherwise distributed by LICENSEE -- or, in the case of a SUBLICENSEE's policy, by said SUBLICENSEE -- and must specify MICHIGAN, including its Regents, fellows, officers and employees, as an additional insured. LICENSEE shall furnish certificate(s) of such insurance to MICHIGAN, upon request.

10.4 In no event shall either party hereunder be liable to the other for any special, indirect, or consequential damages of any kind whatsoever resulting from any breach or default of this Agreement.

ARTICLE 11 -TERM AND TERMINATION

11.1 If LICENSEE ceases to carry on its business, this Agreement shall terminate upon written notice by MICHIGAN attempted to be delivered to the address for notices provided in Article 13.

11.2 If LICENSEE fails to make any payment due to MICHIGAN, upon ten (10) days' written notice by MICHIGAN, this Agreement shall automatically terminate unless MICHIGAN specifically extends such date in writing. Such termination shall not foreclose MICHIGAN from collection of any amounts remaining unpaid or seeking other legal relief.

11.3 Upon any material breach or default of this Agreement by LICENSEE (other than as specifically provided herein, the terms of which shall take precedence over the handling of any other material breach or default under this Paragraph), MICHIGAN has the right to terminate this Agreement effective on thirty (30) days' written notice to LICENSEE. Such termination shall become automatically effective upon expiration of the thirty day period unless LICENSEE cures the material breach or default before the period expires.

11.4 LICENSEE has the right to terminate this Agreement at any time on ninety (90) days' written notice to MICHIGAN if LICENSEE first:

- (a) pays all amounts due MICHIGAN through the effective date of the termination;
- (b) submits a final report of the type described in Paragraph 4.2;
- (c) returns any patent documentation (including that exchanged under Article 7) and any other confidential or trade-secret materials provided to LICENSEE by MICHIGAN in connection with this Agreement, or, with prior approval by MICHIGAN, destroys such materials, and certifies in writing that such materials have all been returned or destroyed;
- (d) suspends its manufacture, use and sale of the LICENSED PROCESS(ES) AND LICENSED PRODUCT(S);
- (e) provides MICHIGAN with all data and know-how developed by LICENSEE in the course of LICENSEE's efforts to develop LICENSED PRODUCTS and LICENSED PROCESSES; MICHIGAN shall have the right to use such data and know-how for any purpose whatsoever, including the right to transfer same to future licensees; and
- (f) provides MICHIGAN access to any regulatory information filed with any U.S. or foreign government agency with respect to LICENSED PRODUCTS and LICENSED PROCESSES.

Upon notice of intent to terminate, MICHIGAN may elect to immediately terminate this Agreement upon written notice.

11.5 Upon any termination of this Agreement, and except as provided herein to the contrary, all rights and obligations of the parties hereunder shall cease, except any previously accrued rights and obligations and further as follows:

- (1) obligations to pay royalties and other sums, or to transfer equity or other consideration, accruing hereunder up to the day of such termination, whether or not this Agreement provides for a number of days before which actual payment is due and such date is after the day of termination;
- (2) MICHIGAN's rights to inspect books and records as described in Article 4, and LICENSEE's obligations to keep such records for the required time;
- (3) any cause of action or claim of LICENSEE or MICHIGAN accrued or to accrue because of any breach or default by the other party hereunder;
- (4) the provisions of Articles I, 9, 10, and 14; and
- (5) all other terms, provisions, representations, rights and obligations contained in this Agreement that by their sense and context are intended to survive until performance thereof by either or both parties.

11.6 After the license(s) granted herein terminate, if LICENSEE has filed patent applications or obtained patents to any modification or improvement to LICENSED PRODUCTS or LICENSED PROCESSES within the scope of the PATENT RIGHTS, LICENSEE agrees upon request to enter into good faith negotiations with MICHIGAN or MICHIGAN's future licensee(s) for the purpose of granting licensing rights to said modifications or improvements in a timely fashion and under commercially reasonable terms.

11.7 If LICENSEE asserts the invalidity or unenforceability of any claim included in the PATENT RIGHTS, including by way of litigation or administrative proceedings, either directly or through any other party, then MICHIGAN shall have the right to immediately terminate this Agreement upon written notice to LICENSEE.

ARTICLE 12 - REGISTRATION AND RECORDATION

12.1 If the terms of this Agreement, or any assignment or license under this Agreement are or become such as to require that the Agreement or license or any part thereof be registered with or reported to a national or supranational agency, LICENSEE will, at its expense, undertake such registration or report. Prompt notice and appropriate verification of the act of registration or report or any agency ruling resulting from it will be supplied by LICENSEE to MICHIGAN upon request.

12.2 LICENSEE shall also carry out, at its expense, any formal recordation of this Agreement or any license herein granted that the law of any country requires as a prerequisite to enforceability of the Agreement or license in the courts of any such country or for other reasons, and shall promptly furnish to MICHIGAN appropriately verified proof of recordation.

ARTICLE 13 - NOTICES

13.1 Any notice, request, or report required or permitted to be given or made under this Agreement by either party is effective when mailed if sent by recognized overnight carrier, certified or registered mail, or electronic mail followed by confirmation by U.S. mail, to the address set forth below or such other address as such party specifies by written notice given in conformity herewith. Any notice, request, or report not so given is not effective until actually received by the other party.

To MICHIGAN:

The University of Michigan
Innovation Partnerships
1600 Huron Parkway
Building 520 2nd Floor
Ann Arbor, MI 48109
Attn: [***]

To LICENSEE:

Ascentage Pharma Group Corp. Ltd.
Unit B,17/F., United Centre, 95
Queensway, Admiralty, Hong Kong
Attn: Dajun Yang, President and CEO

ARTICLE 14 - MISCELLANEOUS PROVISIONS

14.1 This Agreement shall be construed, governed, interpreted and applied according to United States and state of Michigan law, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was granted.

14.2 The parties hereby consent to the jurisdiction of the courts in the state of Michigan over any dispute concerning this Agreement or the relationship between the parties. Should LICENSEE bring any claim, demand or other action against MICHIGAN, its Regents, fellows, officers, employees or agents, arising out of this Agreement or the relationship between the parties, LICENSEE agrees to bring said action only in the Michigan Court of Claims.

14.3 MICHIGAN and LICENSEE agree that this Agreement sets forth their entire understanding concerning the subject matter of this Agreement. The parties may amend this Agreement from time to time, but no modification will be effective unless both MICHIGAN and LICENSEE agree to it in writing.

14.4 If a court of competent jurisdiction finds any term of this Agreement invalid, illegal or unenforceable, that term will be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

14.5 LICENSEE agrees to mark the LICENSED PRODUCTS sold in the United States with all applicable United States patent numbers. All LICENSED PRODUCTS shipped to or sold in other countries shall be marked to comply with the patent laws and practices of the countries of manufacture, use and sale.

14.6 No waiver by either party of any breach of this Agreement, no matter how long continuing or how often repeated, is a waiver of any subsequent breach thereof, nor is any delay or omission on the part of either party to exercise or insist on any right, power, or privilege hereunder a waiver of such right, power or privilege. In no event shall any waiver be deemed valid unless it is in writing and signed by an authorized representative of each party.

14.7 LICENSEE agrees to refrain from using and to require SUBLICENSEES to refrain from using the name of MICHIGAN in publicity or advertising without the prior written approval of MICHIGAN. Reports in scientific literature and presentations of joint research and development work are not publicity. Notwithstanding this provision, without prior written approval of MICHIGAN, LICENSEE and SUBLICENSEES may state publicly that LICENSED PRODUCTS and PROCESSES were developed by LICENSEE based upon an invention(s) developed at the University of Michigan and/or that the PATENT RIGHTS were licensed from the University of Michigan.

14.8 LICENSEE agrees to comply with all applicable laws and regulations. In particular, LICENSEE understands and acknowledges that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations prohibit or require a license for the export of certain types of technical data to certain specified countries. LICENSEE agrees to comply with all United States laws and regulations controlling the export of commodities and technical data, to be solely responsible for any violation of such laws and regulations by LICENSEE or its SUBLICENSEES, and to defend, indemnify and hold harmless MICHIGAN and its Regents, fellows, officers, employees and agents if any legal action of any nature results from the violation.

14.9 The relationship between the parties is that of independent contractor. Neither party is an agent of the other in connection with the exercise of any rights hereunder, and neither has any right or authority to assume or create any obligation or responsibility on behalf of the other.

14.10 LICENSEE may not assign this Agreement without the prior written consent of MICHIGAN and shall not pledge any of the license rights granted in this Agreement as security for any creditor. Any attempted pledge of any of the rights under this Agreement or assignment of this Agreement without the prior consent of MICHIGAN will be void from the beginning. No assignment by LICENSEE will be effective until the intended assignee agrees in writing to accept all of the terms and conditions of this Agreement, and such writing is provided to MICHIGAN. Notwithstanding, LICENSEE may, without MICHIGAN's consent, assign its rights under this Agreement to a purchaser of all or substantially all of LICENSEE's business relating to the subject matter of this Agreement, so long as such assignee provides a statement in writing to MICHIGAN that it agrees to accept all the terms and conditions of this Agreement in the place of LICENSEE.

14.11 If during the term of this Agreement, LICENSEE makes or attempts to make an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy or insolvency are instituted on behalf of or against LICENSEE, or if a receiver or trustee is appointed for the property of LICENSEE, this Agreement shall automatically terminate. LICENSEE shall notify MICHIGAN of any such event mentioned in this Paragraph as soon as reasonably practicable, and in any event within five (5) days after any such event.

ARTICLE 15 - CONFLICT OF INTEREST MANAGEMENT

15.1 This Agreement and the licenses granted hereunder are subject to approval by a two- thirds majority vote of the Regents of the University of Michigan.

15.2 Unless MICHIGAN provides appropriate formal approvals, continuing development of LICENSED PRODUCTS and LICENSED PROCESSES will take place without the use of MICHIGAN funds, facilities, or other resources of or funds administered by MICHIGAN.

15.3 LICENSEE shall cooperate with MICHIGAN in developing and implementing appropriate plans for management of potential conflicts of interest and conflicts of commitment of MICHIGAN employees.

IN WIINESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

For:	LICENSEE	For:	The Regents of the University of Michigan
By:	<u>/S/ Dajun Yang, M.D., Ph.D.</u> (authorized representative)	By:	<u>/S/ Bryce Pilz</u>
Name:	Dajun Yang, M.D., Ph.D.	Name:	
Title:	Chairman & CEO	Title:	
Date:	<u></u>	Date:	<u></u>

Exhibit A



Ascentage Pharma Group Inc.
700 King Farm Boulevard
Suite 510
Rockville, Maryland 20850 USA

June 30, 2025

Veet Misra, PhD
2260 North Point
Suite 1
San Francisco, 94123

Via Electronic Mail

Dear Veet,

It gives us great pleasure to extend our offer of employment to you as our **Chief Financial Officer** for Ascentage Pharma Group Inc. (the "Company") on the terms set forth or referred to in this offer letter ("Offer Letter"). This Offer Letter supersedes any previous offer made to you by the Company whether in writing, orally or in any other form.

Please return a signed copy of this Offer Letter within 48 hours, **on or before July 2, 2025** to indicate your interest and that you accepted the offer. Please note that your acceptance of this Offer Letter is conditional on you signing the Employee Confidentiality and Proprietary Information Agreement and completion of a customary background check satisfactory to the Company.

If you accept our Offer Letter, your employment will commence on **July 7, 2025 (or another mutually agreed upon date)** ("Date of Employment"), until such time it is terminated as provided below in this Offer Letter.

COMPENSATION

Your compensation and employee benefits will be as follows:

- (a) During the term of your employment by the Company, you will be entitled to a *semi-monthly* (15th & 30th of each month) salary of **\$21,875 USD** (prorated for any period of less than a full month), payable in accordance with our standard payroll practices and subject to deductions for applicable federal, state, and local withholding.
-

- (b) According to the terms of the Company's short-term incentive program, you will be eligible for an annual performance bonus, at the target percentage of **40%** of your annual base salary. The bonus is based on your performance measured against your specific individual goals and departmental goals, and the Company's performance of the annual corporate goals as determined by the Board of Directors of the Ascentage Pharma Group International ("Board"). If employed with the Company at the time of the annual bonus distribution, the Company will pay the annual performance bonus, subject to your performance appraisal results, and the Board's determination of the Company's performance of the yearly corporate goals.

- (c) You will be granted under the following equity awards:

Sign-on Incentive

- a. Under the 2022 Restricted Share Unit Scheme, amended, of Ascentage Pharma Group International (the "Plan"), **\$1,500,000** of restricted share units (RSUs) to vest in equal tranches over a four year period beginning with the first tranche vesting after the first anniversary of the Date of Employment and subject to specific approval from the Board of Directors and compliance with the relevant laws and regulations (including the Rules Governing The Listing Of Securities On The Stock Exchange Of Hong Kong Limited), on such terms and provisions as are contained in the RSU grant letter and the Plan;
- b. Under the Post IPO Share Option Scheme, as amended, of Ascentage Pharma Group International (the "Plan"), **\$500,000** of Share Options to vest in equal tranches over a four year period beginning with the first tranche vesting after the first anniversary on or about the Date of Employment, and subject to specific approval from the Board of Directors and compliance with the relevant laws and regulations (including the Rules Governing The Listing Of Securities On The Stock Exchange Of Hong Kong Limited), on such terms and provisions as are contained in the Post IPO grant letter and the Plan;

Annual Performance Incentive

- c. Under the 2022 Restricted Share Unit Scheme, as amended, of Ascentage Pharma Group International (the "Plan"), **\$600,000** of restricted share units (RSUs) to vest based on the successful attainment of specific performance measures, and subject to specific approval from the Board of Directors and compliance with the relevant laws and regulations (including the Rules Governing The Listing Of Securities On The Stock Exchange Of Hong Kong Limited), on such terms and provisions as are contained in the RSU grant letter and the Plan;
- d. Under the Post IPO Share Option Scheme, as amended, of Ascentage Pharma Group International (the "Plan"), **\$600,000** of Share Options to vest based on the successful attainment of specific performance measures, and subject to specific approval from the Board of Directors and compliance with the relevant laws and regulations (including the Rules Governing The Listing Of Securities On The Stock Exchange Of Hong Kong Limited), on such terms and provisions as are contained in the RSU grant letter and the Plan.

EMPLOYEE BENEFIT PLANS

During your employment with the Company, you will be eligible to receive **paid time off (PTO) of 22** days in accordance with our standard policies and to participate in all group benefits plans made available generally to employees of the Company. You are also eligible to receive **two (2) floating holidays** according to company policy to use as you deem appropriate. The Company presently intends to match 401(k) employee contributions up **to 6% of your base salary**. The Company reserves the right to amend, modify, or terminate its policies and benefit plans at any time.

EXCLUSIVE SERVICE AND REPORTING

During your employment by the Company, you will devote all your business and professional time, energy, business judgment, knowledge, skill, and best efforts to the performance of your employment duties with the Company. You will report to **Dajun Yang**, President at Ascentage Pharma Group Inc.

EMPLOYEE HANDBOOK AND OTHER POLICIES

You will be bound by the employment terms contained in the Company’s Employee Handbook and other written policies of the Company in effect from time to time and be required to sign the Company’s standard acknowledgment form as verification of acceptance.

RIGHT TO WORK STATUS

Under the Immigration Reform and Control Act, the Company is required to verify the identity and work authorization of all newly hired employees. Therefore, you will be required to complete the I-9 Form upon your first day of employment. Within three business days of beginning your employment, you also will need to supply acceptable documentation (as noted on the I-9 Form) of your identity and work authorization.

BACKGROUND CHECK AND EMPLOYEE CONFIDENTIALITY AND PROPRIETARY INFORMATION AGREEMENT

This offer is subject to our completion of a customary background check satisfactory to us as well as your execution of the Company’s Employee Confidentiality and Proprietary Information Agreement.

NATURE OF “AT WILL” EMPLOYMENT

If you accept this offer, your employment will be “at will,” which means that either you or the Company may terminate your employment relationship at any time, with or without cause. This means, among other things, that upon the termination of your employment relationship, the Company’s sole obligation to you will be to pay you any accrued and unpaid salary, plus any unreimbursed business expenses and accrued but unused paid time off as provided herein, through the termination date and any benefits in accordance with the Company’s employee benefit plans in which you are then participating as provided therein.

* * * * *

If you require further clarification or information, please contact Lily Cheng, Human

If the terms of employment outlined in this Offer Letter are acceptable to you, please sign and date a copy of this Offer Letter where indicated below and return it to Lily Cheng. You can email it to Lily Cheng at lily.cheng@ascentage.com.

Upon execution by you, this Offer Letter will replace any prior or contemporaneous oral or written understanding or agreement concerning the terms of employment between you and the Company.

This Offer Letter and any dispute concerning the validity, enforceability, or interpretation of this Offer Letter or the terms of your employment will be governed by the internal laws of the State of Maryland without regard to conflict-of-law principles.

We look forward to you joining our team and to a mutually rewarding relationship.

Sincerely,

/s/ Dajun Yang

Dajun Yang, Ph.D.

President

Ascentage Pharma Group Inc.

Acknowledgment

I hereby accept the offer on the terms set forth above and acknowledge this agreement with the Company and that no other terms, conditions, or representations other than those contained herein form part of this agreement. I understand that my employment relationship is on an “at-will” basis and can be terminated by either the Company or myself at any time, with or without cause. I hereby represent and warrant to the Company that (a) I have the legal right to accept this offer of employment and to perform my employment obligations hereunder and (b) am not a party to any agreement or understanding, and am not subject to any restriction, which, in either case, could prevent me from entering into this agreement or performing my employment duties hereunder.

July 3, 2025
DATE

Veetshok Misra

PRINT FULL NAME

/S/ Veetshok Misra

FULL SIGNATURE

Subsidiaries of registrant*

Name of Subsidiary	Jurisdiction of Incorporation
Ascentage Pharma Group Corp Limited	Hong Kong
Jiangsu Ascentage Pharma Co., Limited	People's Republic of China
Guangzhou Healthquest Pharma Co., Ltd.	People's Republic of China
Ascentage International Limited	Hong Kong
Ascentage Pharma Group Inc.	United States
Shanghai Yasheng Pharmaceutical Technology Co., Ltd.	People's Republic of China
Ascentage Pharma Pty. Ltd.	Australia
Suzhou Ascentage Pharma Co., Ltd.	People's Republic of China
Ascentage Investment International	Cayman Islands
Ascentage Investment Limited	Hong Kong
Suzhou Ascentage Grains Valley Venture Capital Co., Ltd.	People's Republic of China
Shanghai UUBiopharma Co., Ltd.	People's Republic of China
Ascentage Pharma Europe Limited	Ireland
Shanghai Centagen Pharma Co., Ltd.	People's Republic of China
Suzhou Shenghe Innovation Works Biotech Co., Ltd.	People's Republic of China
Suzhou Gsun No. 8 Equity Investment Partnership (Limited Partnership)	People's Republic of China
Suzhou Shenghe Innovation Space Development Co., Ltd.	People's Republic of China

* The English names of the companies registered in the People's Republic of China represent the best efforts made by the management of the registrant in directly translating the Chinese names of these companies as no English names have been registered.

ASCENTAGE PHARMA GROUP INTERNATIONAL

INSIDER TRADING POLICY

Ascentage Pharma Group International (6855.HK) (the “**Company**”) and its subsidiaries and affiliates (together, the “**Group**”) are committed to ensuring that all of its shareholders and potential shareholders can buy and sell the Company’s securities fairly. Shareholders and potential shareholders must have confidence that Company’s board of directors (“**Directors**”), officers, employees, and agents, as well as the board of directors, officers, employees, and agents of any member of the Group, cannot derive an unfair advantage as a result of their access to Inside Information. Accordingly, all directors, officers, employees and agents are required to deal in shares and handle Inside Information in accordance with this Insider Trading Policy (“**Policy**”). This Policy also serves to protect the reputation of Company and help protect its and its affiliates directors, officers, employees, and agents and Company from civil and criminal liability.

This Policy provides guidelines to the directors, officers, employees and agents of any member of the Group with respect to transactions in the Company’s securities and codifies the Company’s standards on trading and enabling the trading of securities of the Company or other publicly-traded companies while in possession of Inside Information.

The basis for this Policy and all actions by the directors, officers, employees and agents of any member of the Group must be in compliance with laws applicable to the trading of the Company’s securities. Specifically, it is the policy of the Company to observe fully the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) (the “**SFO**”) and the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”).

1. Scope of Policy

The provisions of this Policy apply to all directors, officers, employees, consultants and contractors of the Company, each of whom and all Associates of such persons (collectively, “**Restricted Persons**”), will agree to be bound by such provisions upon being notified of the most recent copy of this Policy.

The provisions of this Policy apply to all transactions in the Company’s securities, including common or preferred stock, options and warrants to purchase common stock, notes, restricted share unit, bonds, convertible securities and any other debt or equity securities that the Company may issue from time to time (collectively, “**Company Securities**”).

2. Exceptions for certain Transactions

This Policy does not apply to all transactions involving the Company Securities. The following exceptions are intended to facilitate several common types of transactions.

- (a) Stock Option Exercises. This Policy does not apply to the mere exercise of a stock option for cash under the Company’s stock option plans. This Policy does apply, however, to:
 - i. Any sale of stock as part of a broker-assisted “cashless” exercise of an option (*i.e.*, any market sale for the purpose of generating the cash needed to pay the exercise price of an option); and
 - ii. Any sale of shares of Company stock received upon exercise of an option.

- (b) Net Settlement upon Vesting of Restricted Stock. This Policy does not apply to a surrender of shares to the Company or the retention and withholding from delivery to the applicable officer, director or employee of shares by the Company (*i.e.*, a so-called “net settlement”) upon vesting of restricted stock in satisfaction of any tax withholding obligations in a manner permitted by the applicable grant letter or the Company plan pursuant to which the restricted stock was granted.

3. **Trading Prohibition**

Insider trading occurs when a person in possession of Inside Information obtained through involvement with the Company (1) uses that information to make decisions to purchase, sell, or otherwise trade in securities of the Company or another company, or (2) provides that information to others to enable such trading.

No directors, officers, employees, consultants and contractors of any member of the Group:

- (a) may purchase or sell any Company Securities while in possession of Inside Information about the Company, its customers, suppliers, consultants or other companies with which the Company has contractual relationships or may be negotiating transactions;
- (b) may communicate any Inside Information about the Company to any other person;
- (c) may purchase or sell any security of any other company, whether or not issued by the Company, while in possession of Inside Information about that company that was obtained in the course of his or her involvement with the Company;
- (d) should ever trade, tip or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that he or she has reason to believe is Inside Information. Every director, officer, employee, consultant and contractor of any member of the Group must consult with the Compliance Representative to trade in Company Securities.

Other trading prohibitions

The Company considers it improper and inappropriate for directors, officers, employees, consultants and contractors of any member of the Group to engage in short-term or speculative transactions in the Company’s securities or in other transactions that may lead to inadvertent violations of the insider trading laws. Accordingly, trading in the Company’s securities by directors, officers, employees, consultants and contractors of any member of the Group is subject to the following additional restrictions:

- (a) Short sales. No directors, officers, employees, consultants and contractors of any member of the Group may sell the Company Securities short (sale of stock that the seller does not own or a sale that is completed by delivery of borrowed stock).

- (b) Options trading. No directors, officers, employees, consultants and contractors of any member of the Group may buy or sell puts or calls or other derivative securities on the Company Securities.
- (c) Trading on margin; Pledging. No directors, officers, employees, consultants and contractors of any member of the Group may hold Company Securities in a margin account or pledge Company Securities as collateral for a loan.
- (d) Hedging. No directors, officers, employees, consultants and contractors of any member of the Group may enter into hedging, monetization transactions, or similar arrangements with respect to Company Securities.

4. **Blackout Periods**

All directors, officers, employees and agents of any member of the Group are prohibited from trading in the Company's securities during the following Blackout Periods:

- (a) Announcement of annual and interim financial results: on any day on which the financial results are published and (a) during the period of 60 days immediately preceding the publication date of annual results or, if shorter, the period from the end of the relevant financial year up to the publication date of the results or (b) during the period of 30 days immediately preceding the publication date of the quarterly results (if any) and half-year results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results;
- (b) Special Blackout Periods. From time to time, while the following material non-public information is pending, the Company may impose special blackout periods to those persons who may have material non-public information regarding the Company (such as negotiation of mergers, acquisitions or dispositions, new product developments, read-outs from clinical trials, or other material events) that may be pending and not yet publicly disclosed. Before or during the Special Blackout Periods, the Company may also require such persons to execute acknowledgment letter or such other documents as may be necessary to comply with the applicable laws or the Listing Rules; and
- (c) when you are in possession of Inside Information.

5. **Pre-Clearance Requirements**

Directors, officers and employees of the Company with the title of vice president or higher must obtain prior clearance from the Compliance Representative (as defined below) before they or their Associate makes any purchases or sales of the Company Securities. A detailed procedure and requirement for pre-clearance is attached as Exhibit A.

In addition, employees of the Company with the title of Chief Officer (including CEO, CFO, CBO, CCO, CMO, etc., hereinafter referred to as "**C-level Employees**"), must obtain prior approval from the CFO and CEO of the Company (in the case of the CEO, prior approval must first be obtained from the Compliance Representative followed by the CFO; and in the case of the CFO, prior approval must first be obtained from the Compliance Representative followed by the CEO), before they or their Associates can make any purchases or sales of the Company Securities, and shall notify the Secretary of the Board of Directors to file any necessary filings as required by applicable law or the Listing Rules.

6. Violations of Insider Trading Laws

Penalties for trading on or communicating Inside Information can be severe, both for the Company and the directors, officers, employees and agents of any members of the Group. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory. A summary of the consequences of violating this Policy is attached as Exhibit B.

Individuals who violate this Policy may be subject to disciplinary action by the Company, up to and including dismissal for cause. Any exemptions from strict compliance with the Policy, if permitted, may only be granted by the Compliance Representative in writing and must be provided before any activity contrary to the above requirements takes place.

7. Compliance Representative

The Company has appointed its Compliance Representative for this Policy. The duties of the Compliance Representative include, but are not limited to, the following:

- (a) assisting with the implementation of this Policy;
- (b) circulating this Policy to all Company and its affiliates directors, officers, employees, and agents of the Company and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws; and
- (c) pre-clearing all trading in securities of the Company by employees of the Company with the title of vice president or higher (except for C-level Employees) in accordance with the procedures set forth in Section 5 of this Policy.

In the event that the Compliance Representative is unavailable, the Company shall designate another appropriate person to assume the responsibilities during the time of the Compliance Representative's unavailability.

8. Questions About the Policy

Any question about this Policy or any related processes should be directed to the Compliance Representative. Violations of this Policy must be reported to the Compliance Representative.

9. Definitions

- (a) **Associate.** In relation to a person, means the person's spouse or reputed spouse, any person cohabiting with the person as a spouse, the person's brother, sister, parent, step-parent, child (natural or adopted) or step child; and any corporation of which the person is a director, or any employee or partner of the person, and to transactions by entities over which such person is a director, employee or partner, or can exercises control over such entities, and such other person as defined as Associate by Part XIV the SFO (as amended from time to time).

- (b) **Compliance Representative.** Means any senior officer, designated from time to time by the Company. The Company hereby appointed Thomas J. Knapp as the Compliance Representative dealing with all the compliance issue for the Company's affiliate company located in US, Australia and European countries, and Jun Yan as the Compliance Representative dealing with all the compliance issue for the Company's affiliate company located in Cayman Islands, Hong Kong SAR and Mainland China.
- (c) **Inside Information.** Means specific information that (a) is about the Company, any shareholder or officer of the company, or the listed securities of the company or their derivatives and (b) is not generally known to the persons who are accustomed or would be likely to deal in the Company securities but would if generally known to them be likely to materially affect the price of the Company securities. A detailed guideline for determining Inside Information is attached as Exhibit C.

10. Miscellaneous

This Policy shall come into force with effect from the date as executed by the CEO of the Company and replace the previous insider trading policy as adopted on June 21, 2018.

This Policy is written in both Chinese and English, in case of any conflict between the Chinese version and the English version, the English version shall prevail.

This Policy may be amended from time to time. Any amendments to this Policy shall be approved by the Company and will be communicated to directors, officers, employees, consultants and contractors of any member of the Group.

Name:
Title:
Ascentage Pharma Group International

EXHIBIT A

ASCENTAGE PHARMA GROUP INTERNATIONAL

TRADING POLICY PROCEDURES FORM

In accordance with Ascentage Pharma Group International's Insider Trading Policy, before trading in any securities of Ascentage Pharma Group International ("**Company**"), you are required to follow the following pre-clearance procedures.

- (a) The Company requires all Directors, officers and employees of the Company with the title of vice president or higher (the "**Pre-Clearance Applicant**") to obtain prior clearance from the Compliance Representative before they or any of their Associate makes any purchases or sales of the Company Securities.
- (b) The Pre-Clearance Applicant shall submit the application with all the required information attached and the executed Trading Notification Form (see below for the format) to the Compliance Representative through the OA system of the Company, or other method acceptable to the Company. Such application shall be initiated at least 3 trading days before the date that the Applicant desires to trade the Company Securities, and the Compliance Representative shall approve, or reject the application (if he believes the trading as proposed by such application will be a violation of the applicable laws) within 2 trading days.
- (c) Unless revoked, a grant of permission will normally remain valid for five (5) trading days. If the transaction does not occur during that specified time period, pre-clearance of the transaction must be re-requested.
- (d) The Company may impose a volume restriction on the number of Company Securities that may be traded by the directors, officers, employees, consultants and contractors of any member of the Group. In such an event, the Company will notify all the directors, officers, employees, consultants and contractors of any member of the Group who will be subject to such restriction, of such volume restriction and the length of time such volume restriction will be in effect.

Trading Notification Form

Version: March 2021

Unless otherwise defined, capitalized terms used in this form shall have the same meanings as those defined in the Insider Trading Policy of Ascentage Pharma Group International (the “*Company*”).

In accordance with the Company’s Insider Trading Policy, before dealing in any Company Securities, you are required to provide written notification of your intent to trade through OA. You will receive a notification in OA or Human Resources if the proposed trading transaction has been cleared and the period of time the clearance is effective.

Each individual wishing to trade shares must complete and submit the form below for pre- clearance/approval:

Name :
Title:
Phone No. :
E-mail :

_____ (please initial) I hereby provide written notification of my intent to trade in the following Company Securities, which are held or proposed to be held by myself personally and/or by an Associate as follows:

Stock Name (Stock Code)	Number of Securities/Derivatives	Type of Transaction (Disposal, Acquisition, Acceptance, Exercise)
Ascentage Pharma Group Intl (6855.HK)		

_____ (please initial) I have read the Insider Trading Policy and confirm that I am in compliance with such policy for trading the abovementioned Company Securities.

_____ (please initial) I confirm that I will not trade, through myself or through my Associate in the Company Securities: on any day on which the financial results are published and (a) during the period of 60 days immediately preceding the publication date of annual results or, if shorter, the period from the end of the relevant financial year up to the publication date of the results or (b) during the period of 30 days immediately preceding the publication date of the quarterly results (if any) and half-year results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results;

_____ (please initial) I confirm that I will not deal, through myself or through Associate of mine, in the Company Securities during the Special Blackout Periods, (ii) when I am in possession of inside information; and (iii) where clearance to trade has not yet received.

_____ (please initial) I confirm that I am not aware of any confidential, Inside Information that is likely to materially affect the Company's stock price during the clearance time period.

_____ (please initial) I understand that acknowledgement of this written notification will not necessarily provide to me or the Associate any defense against any statutory liability and/or any charge of insider dealing or market misconduct.

Signed: _____

Date: _____

Print Name:

Acknowledgment

_____ (please initial) I acknowledge that the required information has been provided above.

_____ (please initial) Each written acknowledgment is valid for a specified period following the date of the acknowledgment, and the trading must be completed in that clearance time period. After this time, a new written notification must be submitted.

Signed: _____

Date: _____

Print Name:

Summary of Insider Dealing and Market Misconduct Provisions

1 Types of Market Misconduct

There are six types of market misconduct relating to dealings in securities:

- insider dealing
- false trading
- price rigging
- disclosure of information about prohibited transactions
- disclosure of false or misleading information inducing transactions
- stock market manipulation

2 The Prohibition on Insider Dealing

- 2.1 The Company's substantial shareholders, directors and employees, plus its advisers are prohibited from dealing in the Company's shares (or in those of a related corporation) at a time when:
- a) they possess information which is not known to people who would be likely to deal in those shares if they knew it; and
 - b) which information (if known) would be likely to affect the price of the shares materially. (*Section 270, SFO*)
- 2.2 The offence extends to asking or encouraging another person to deal, and to giving them information, knowing or having reasonable cause to believe that the other person will deal.
- 2.3 It is not only individuals that can be accused of insider dealing. Corporations are imputed with the knowledge of their directors and employees. Therefore, in certain circumstances, if the Company deals in another listed company's shares at a time when one of its directors or employees is in possession of Inside Information, the Company may be guilty of insider dealing too.

3 Other Market Misconduct

- 3.1 False trading takes place where a person does anything with the intention that it creates a false or misleading appearance of:
- a) active trading in securities;
 - b) the market for securities; or
 - c) the price for dealing in securities;
- or being reckless as to whether it would have that effect. (*Sections 274 and 295, SFO*)

- 3.2 Price rigging occurs when a person enters into an artificial transaction which has the effect of maintaining, increasing, reducing, stabilizing or causing fluctuations in the price of securities. (*Sections 275 and 296, SFO*)
- 3.3 The offence of disclosing information about prohibited transactions takes place when a person discloses, or authorizes or is concerned in the disclosure of, information about a transaction which constitutes market misconduct and where he (or his associate) carried out the market misconduct or expects to benefit as a result of the disclosure. (*Sections 276 and 297, SFO*)
- 3.4 The offence of disclosing false or misleading information takes place when a person discloses false or misleading information which is likely either to induce others to invest, or to affect the price of securities and the person knows that or is reckless or negligent as to whether the information is false or misleading. (*Sections 277 and 298, SFO*)
- 3.5 Stock market manipulation occurs when a person carries out two or more transactions in relation to securities of a corporation that by themselves, or in conjunction with other transactions, increase, reduce, maintain or stabilize (or are likely to do so) the price of any traded securities, with the intention of inducing another person to purchase or sell (or refrain from purchasing or selling) securities of that corporation. (*Sections 278 and 299, SFO*)
- 3.6 Examples of activities that will usually amount to false trading, price rigging and/or market manipulation are wash sales (where a person uses a nominee to buy and sell shares without the beneficial owner changing) and matched orders (where a person agrees to buy shares at the same price as he has agreed to sell the same number of shares).
- 3.7 The activities set out in paragraphs 3.1 to 3.6 above are, like insider dealing, both criminal and civil offences in Hong Kong. There are some additional types of misconduct that are only criminal offences. These are:
- a) offences involving fraudulent or deceptive devices in transactions in securities, futures contracts or leveraged foreign exchange trading (*Section 300, SFO*);
 - b) offences of disclosure of false or misleading information inducing others to enter into leveraged foreign exchange contracts (*Section 301, SFO*); and
 - c) offences of falsely representing dealings in futures contracts on behalf of others (*Section 302, SFO*).

4 Consequences of Breach

- 4.1 All six types of market misconduct are criminal offences, punishable in court by a fine of up to HK\$10 million and imprisonment for up to 10 years. Most are also civil offences and will be investigated by the Market Misconduct Tribunal in Hong Kong (“**MMT**”).
- 4.2 The MMT was established to make it easier to prosecute market participants for behavior which now constitutes market misconduct. The MMT has wide-ranging powers to investigate and obtain evidence in relation to misconduct. Although the penalties for breaches prosecuted by the MMT (rather than through the courts) are less severe, it is generally considerably easier for a person to be called to account than it was in the past.

4.3 The MMT has the power to make the following orders:

- a) a “disqualification order”, preventing the person from being a director, liquidator, receiver or otherwise being involved in the management of the listed company for a period of up to 5 years without the approval of the court ;
- b) a “cold shoulder order”, preventing that person from acquiring, disposing or otherwise dealing in securities, futures, leveraged foreign exchange contracts or collective investment schemes for a period of up to 5 years without the approval of the court;
- c) a “cease and desist order”, preventing that person from being involved in any further market misconduct;
- d) a “disgorgement order”, requiring the person to pay to the Government an amount up to the profit obtained;
- e) a “costs order”, requiring the person to pay to the investigating authority an amount considered to be appropriate to compensate for the costs of the investigation; and
- f) a “disciplinary referral order”, requiring that disciplinary action be taken against the person.

4.4 A person who commits market misconduct may also be liable to compensate a person who suffers loss as a result of the misconduct.

5 Obligation to Take Steps to Prevent Market Misconduct

The directors, managers, secretary and senior management of the Company are required to take all reasonable measures to ensure that proper safeguards exist to prevent the Company from acting in a way which would constitute market misconduct. (*Section 279, SFO*)

6 Takeovers and Insider Dealing

The fact that the Company is considering making a takeover offer for a Hong Kong listed corporation will be Inside Information under the Hong Kong legislation. If the Company decides, as part of the lead-up to the takeover offer, to build a strategic stake in the target, this will be permitted, provided that the purpose of the dealing is for the takeover offer, and not to affect the price of the shares.

Guideline for Determining Inside Information**Public Information**

Information is considered unpublished if it has not been formally announced by Company by way of an announcement published on HKSE website, Company's official website or official WeChat account (or announcement in other form recognized by the Listing Rules). Information will continue to be considered unpublished until the day after the announcement has been published. Statements by the Company's or its affiliates executives are not considered formal announcements that would qualify as publication under the Listing Rules.

Questions Checklist for Determining Inside Information

To determine whether information is Inside Information, an individual should ask the following questions:

- Would a member of the public consider the information necessary to value an investment in the Company or any of its affiliated companies?
- Would the information be necessary to avoid speculation or manipulation of the Company's securities (creation of a false market)?
- Would it be reasonable to expect that the information would affect the price of or market activity in the Company's securities or market activity?

If the answer to any of these questions is "yes," the information is Inside Information.

Examples of Inside Information

Information dealing with the following subjects is reasonably likely to be found as Inside Information:

- regularly recurring matters (such as financial results and dividends);
- exceptional matters (such as acquisitions, connected transactions, strategic alliances, licensing arrangements, collaborations, etc.);
- signing an important contract (including significant joint venture agreements);
- fund-raising exercises;
- comments on the prospects for future earnings or dividends;
- release of any projected profits of the Company by Company or its directors;
- entering into an agreement for the issue of options convertible into securities;
- a large foreign exchange loss;
- major market upheaval in the industries, countries or regions where the company has significant operations or transactions;
- premature removal of auditors before end of their term in office;
- cancellation of an agreement which was previously the subject of an announcement;
- removal or resignation of the chief executive officer;
- the Company being aware that its auditors will issue a qualified report on its results;
- any change of accounting policy that may have a significant impact on the accounts; or

- events beyond the control of the Company and is of material significance to the Company's business, operations or financial performance;
- the timelines or the results of preclinical studies or clinical trials;
- scientific, medical or financial data relating to the Company's products or products under development;
- developments regarding significant litigation or government agency investigations;
- impending bankruptcy or liquidity problems;
- changes in earnings estimates or unusual gains or losses in major operations;
- major changes in management;
- a determination to declare a dividend;
- extraordinary borrowings; and
- actions of regulatory and health agencies, particularly the China and U.S. Food and Drug Administrations.

Uncertainty

As with questions of Inside Information, if you are not sure whether information is considered as Inside Information, you should either consult with the Compliance Representative or assume that the information is Inside Information and treat it as Inside Information.

**Certification of Principal Executive Officer
pursuant to Rule 13a-14(a) of the
Securities Exchange Act of 1934**

I, Dajun Yang, MD, PhD, principal executive officer of Ascentage Pharma Group International (“Ascentage Pharma”), certify that:

1. I have reviewed this Annual Report on Form 20-F for the year ended December 31, 2025 of Ascentage Pharma;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Ascentage Pharma as of, and for, the periods presented in this report;
4. Ascentage Pharma’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 Ascentage Pharma 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 Ascentage Pharma, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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 Ascentage Pharma’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in Ascentage Pharma’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, Ascentage Pharma’s internal control over financial reporting; and
5. Ascentage Pharma’s other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to Ascentage Pharma’s auditors and the audit committee of Ascentage Pharma’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 Ascentage Pharma’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 Ascentage Pharma’s internal control over financial reporting.

Date: April 29, 2026

/s/ Dajun Yang

Dajun Yang, MD, PhD

Chairman of the Board of Directors and Chief Executive Officer

**Certification of Principal Financial and Accounting Officer
pursuant to Rule 13a-14(a) of the
Securities Exchange Act of 1934**

I, Jin Cao, acting principal financial and accounting officer of Ascentage Pharma Group International ("Ascentage Pharma"), certify that:

1. I have reviewed this Annual Report on Form 20-F for the year ended December 31, 2025 of Ascentage Pharma;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Ascentage Pharma as of, and for, the periods presented in this report;
4. Ascentage Pharma'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 Ascentage Pharma 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 Ascentage Pharma, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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 Ascentage Pharma's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in Ascentage Pharma'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, Ascentage Pharma's internal control over financial reporting; and
5. Ascentage Pharma's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to Ascentage Pharma's auditors and the audit committee of Ascentage Pharma'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 Ascentage Pharma'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 Ascentage Pharma's internal control over financial reporting.

Date: April 29, 2026

/s/ Veet Misra

Veet Misra,
Chief Financial Officer

**Certification of Principal Executive Officer
Pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and
Section 1350 of Chapter 63 of Title 18 of the United States Code**

Pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code, Dajun Yang, MD, PhD, Chief Executive Officer (Principal Executive Officer) of Ascentage Pharma Group International (the “Company”), hereby certifies that, to the best of his knowledge:

1. Our Annual Report on Form 20-F for the year ended December 31, 2025, to which this Certification is attached as Exhibit 13.1 (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2026

/s/ Dajun Yang

Dajun Yang, MD, PhD, Chief Executive Officer
(Principal Executive Officer)

This certification accompanies this Annual Report on Form 20-F pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

**Certification of Principal Financial and Accounting Officer
Pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and
Section 1350 of Chapter 63 of Title 18 of the United States Code**

Pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code, Jin Cao, Acting Financial and Accounting Officer of Ascentage Pharma Group International (the “Company”), hereby certifies that, to the best of his knowledge:

1. Our Annual Report on Form 20-F for the year ended December 31, 2025, to which this Certification is attached as Exhibit 13.2 (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2026

/s/ Veet Misra

Veet Misra, Chief Financial Officer

This certification accompanies this Annual Report on Form 20-F pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-284445) pertaining to the Pre-IPO Share Option Scheme, Post-IPO Share Option Scheme, 2018 Restricted Share Unit Scheme, 2021 Restricted Share Unit Scheme and 2022 Restricted Share Unit Scheme of Ascentage Pharma Group International,
- (2) Registration Statement (Form S-8 No. 333-284064) pertaining to the 2022 Restricted Share Unit Scheme of Ascentage Pharma Group International, and
- (3) Registration Statement (Form S-8 No. 333-290285) pertaining to the 2022 Restricted Share Unit Scheme of Ascentage Pharma Group International;

of our report dated April 29, 2026, with respect to the consolidated financial statements of Ascentage Pharma Group International included in this Annual Report (Form 20-F) of Ascentage Pharma Group International for the year ended December 31, 2025.

/s/ Ernst & Young Hua Ming LLP

Shanghai, the People's Republic of China

April 29, 2026

**Partners:**

Paul Aherne **
 Brett Basdeo ***
 John Cartwright *
 John Crook *
 Mark Cummings *****
 Natalie Curtis *****
 James Gaden *****
 Kevin Ho *****
 Kristen Kwok **
 Wing Lam *
 Thomas Pugh *****
 Andrew Randall **
 Victoria Raymond *
 Wei Ching Teo *****

28 April 2026

Our Ref: MRC/BLUI/A6519-H26578

Ascentage Pharma Group International

亞盛醫藥集團
 c/o Walkers Corporate Limited
 190 Elgin Avenue
 George Town
 Grand Cayman KY1-9008, Cayman Islands

Dear Sir or Madam

ASCENTAGE PHARMA GROUP INTERNATIONAL 亞盛醫藥集團

We consent to the reference to our firm under the heading “Item 10. Additional Information—E. Taxation—Cayman Islands taxation” in the Annual Report on Form 20-F of Ascentage Pharma Group International for the fiscal year ended December 31, 2025 (the “**Annual Report**”), which was filed with the U.S. Securities and Exchange Commission (the “**Commission**”) under the U.S. Securities Exchange Act of 1934, as amended (the “**Exchange Act**”) in the month of April 2026.

In addition, we also consent to the inclusion of our opinion as discussed in the heading “Item 10. Additional Information—E. Taxation—Cayman Islands taxation” in the Annual Report and further consent to our opinion as set forth in this Annual Report being incorporated by reference into the Registration Statement on Form S-8 (No. 333-284445).

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under the Exchange Act, or the rules and regulations of the Commission promulgated thereunder.

Yours faithfully

/s/ WALKERS
WALKERS (HONG KONG)

Walkers (Hong Kong)
 選嘉偉師事務所(香港)

15th Floor, Alexandra House, 18 Chater Road, Central, Hong Kong
T +852 2284 4566 F +852 2284 4560

Bermuda | British Virgin Islands | Cayman Islands | Dubai | Guernsey | Hong Kong | Ireland | Jersey | London | Singapore

*England and Wales; **BVI; ***Cayman Islands; ****New South Wales (Australia); *****Bermuda, *****Singapore

26/F HKRI Centre One, HKRI Taikoo Hui,
288 Shimen Road (No. 1),
Shanghai 200041, P.R. China
T: (86-21) 5298-5488
F: (86-21) 5298-5492
junhesh@junhe.com

April 28, 2026

To:

Ascentage Pharma Group International (the “Company”)

190 Elgin Avenue
George Town
Grand Cayman KY1-9008
Cayman Islands

68 Xinqing Road
Suzhou Industrial Park
Suzhou, Jiangsu
China

Dear Sir/Madam,

We consent to the references to our firm under the headings “Item 3. Key Information—C. Risk Factors—Risks related to doing business in the PRC” and “Item 10. Additional Information—E. Taxation—Material People’s Republic of China taxation” in the Company’s Annual Report on Form 20-F for the year ended December 31, 2025 (the “**Annual Report**”), which will be filed with the U.S. Securities and Exchange Commission (the “**Commission**”) under the U.S. Securities Exchange Act of 1934, as amended (the “**Exchange Act**”) on April 28, 2026.

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under the Exchange Act, or the rules and regulations of the promulgated thereunder.

Yours faithfully,

/s/ **JunHe LLP**

JunHe LLP

FROST & SULLIVAN

沙利文

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1717 Nanjing West Road
Shanghai 200040, China
Tel: 86 (21) 5407 5836
Fax: 86 (21) 3209 8500
www.frost.com

April 27, 2026

Ascentage Pharma Group International

68 Xinqing Road
Suzhou Industrial Park
Suzhou, Jiangsu
People's Republic of China

Re: Ascentage Pharma Group International

Ladies and Gentlemen,

We consent to the references to our firm under the headings “Industry and Market Data,” “Item 4. Information on the Company—B. Business Overview” and “Item 5. Operating and Financial Review and Prospects—A. Operating Results” in Ascentage Pharma Group International’s Annual Report on Form 20-F for the year ended December 31, 2025 (the “Annual Report”), which will be filed with the U.S. Securities and Exchange Commission (the “Commission”) under the U.S. Securities Exchange Act of 1934, as amended (the “Exchange Act”) on April 28, 2026.

In addition, we also consent to the inclusion of our opinion as discussed in the headings “Industry and Market Data,” “Item 4. Information on the Company—B. Business Overview” and “Item 5. Operating and Financial Review and Prospects—A. Operating Results” in the Annual Report and further consent to our opinion as set forth in this Annual Report being incorporated by reference into the Registration Statement on Form S-8 (No. 333-284445).

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under the Exchange Act, or the rules and regulations of the Commission promulgated thereunder.

Yours faithfully,

For and on behalf of

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

Signature: /s/ Tracy Wang

Name: Tracy Wang

Title: Consulting Manager

ASCENTAGE PHARMA GROUP INTERNATIONAL

COMPENSATION RECOVERY POLICY

As adopted on February 10, 2025

Ascentage Pharma Group International (the “**Company**”) is committed to strong corporate governance. As part of this commitment, the Company’s Board of Directors (the “**Board**”) has adopted this clawback policy called the Compensation Recovery Policy (the “**Policy**”). The Policy is intended to further the Company’s pay-for-performance philosophy and to comply with applicable laws by providing rules relating to the reasonably prompt recovery of certain compensation received by Covered Executives in the event of an Accounting Restatement. The application of the Policy to Covered Executives is not discretionary, except to the limited extent provided below, and applies without regard to whether a Covered Executive was at fault. Capitalized terms used in the Policy are defined below, and the definitions have substantive impact on its application so reviewing them carefully is important to your understanding.

The Policy is intended to comply with, and will be interpreted in a manner consistent with, Section 10D of the Securities Exchange Act of 1934 (the “**Exchange Act**”), with Exchange Act Rule 10D-1 and with the listing standards of the national securities exchange (the “**Exchange**”) on which the securities of the Company are listed, including any official interpretive guidance.

Persons Covered by the Policy

The Policy is binding and enforceable against all “**Covered Executives**.” A Covered Executive is each individual who is or was ever designated as an “executive officer” by the Board (as defined in Item 401(b) of Regulation S-K under the Exchange Act) (an “**Executive Officer**”). The Committee may (but is not obligated to) request or require a Covered Executive to sign and return to the Company an acknowledgement that such Covered Executive will be bound by the terms and comply with the Policy. The Policy is binding on each Covered Executive whether or not the Covered Executive signs and/or returns any acknowledgment.

Administration of the Policy

The Remuneration Committee (the “**Committee**”) of the Board has full delegated authority to administer the Policy. The Committee is authorized to interpret and construe the Policy and to make all determinations necessary, appropriate, or advisable for the administration of the Policy. In addition, if determined in the discretion of the Board, the Policy may be administered by the independent members of the Board or another committee of the Board made up of independent members of the Board, in which case all references to the Committee will be deemed to refer to the independent members of the Board or the other Board committee. All determinations of the Committee will be final and binding and will be given the maximum deference permitted by law.

Accounting Restatements Requiring Application of the Policy

If the Company is required to prepare 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, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (an “**Accounting Restatement**”), then the Committee must determine the Excess Compensation, if any, that must be recovered. The Company’s obligation to recover Excess Compensation is not dependent on if or when restated financial statements are filed.

Compensation Covered by the Policy

The Policy applies to certain **Incentive-Based Compensation** (certain terms used in this Section are defined below) that is **Received** on or after October 2, 2023 (the “**Effective Date**”), during the **Covered Period** while the Company has a class of securities listed on a national securities exchange. Such Incentive-Based Compensation is considered “**Clawback Eligible Incentive-Based Compensation**” if the Incentive-Based Compensation is Received by a person after such person became an Executive Officer and the person served as an Executive Officer at any time during the performance period for the Incentive-Based Compensation. “**Excess Compensation**” means the amount of Clawback Eligible Incentive-Based Compensation that exceeds the amount of Clawback Eligible Incentive-Based Compensation that otherwise would have been Received had such Clawback Eligible Incentive-Based Compensation been determined based on the restated amounts. Excess Compensation must be computed without regard to any taxes paid and is referred to in the listings standards as “erroneously awarded compensation”.

To determine the amount of Excess Compensation for Incentive-Based Compensation based on stock price or total shareholder return, where it is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the amount must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and the Company must maintain documentation of the determination of that reasonable estimate and provide that documentation to the Exchange.

“**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. For the avoidance of doubt, no compensation that is potentially subject to recovery under the Policy will be earned until the Company’s right to recover under the Policy has lapsed.

“**Financial Reporting Measures**” are measures that are determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

Incentive-Based Compensation is “**Received**” under the Policy 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, vesting, settlement or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, the Policy does not apply to Incentive-Based Compensation for which the Financial Reporting Measure is attained prior to the Effective Date.

“**Covered Period**” means the three completed fiscal years immediately preceding the Accounting Restatement Determination Date. In addition, Covered Period can include certain transition periods resulting from a change in the Company’s fiscal year.

“**Accounting Restatement Determination Date**” means the earliest to occur of: (a) the date the Board, a committee of the Board, or one or more of 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; and (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

Repayment of Excess Compensation

The Company must recover Excess Compensation reasonably promptly and Covered Executives are required to repay Excess Compensation to the Company. Subject to applicable law, the Company may recover Excess Compensation by requiring the Covered Executive to repay such amount to the Company by direct payment to the Company or such other means or combination of means as the Committee determines to be appropriate (these determinations do not need to be identical as to each Covered Executive). These means include (but are not limited to):

- (a) requiring reimbursement of cash Incentive-Based Compensation previously paid;
- (b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards (including, but not limited to, time-based vesting awards), without regard to whether such awards are Incentive-Based Compensation or vest based on the achievement of performance goals;
- (c) offsetting the amount to be recovered from any unpaid or future compensation to be paid by the Company or any affiliate of the Company to the Covered Executive, including (but not limited to) payments of severance that might otherwise be due in connection with a Covered Executive's termination of employment and without regard to whether such amounts are Incentive-Based Compensation;
- (d) cancelling outstanding vested or unvested equity awards (including, but not limited to, time-based vesting awards), without regard to whether such awards are Incentive-Based Compensation; and/or
- (e) taking any other remedial and recovery action permitted by law, as determined by the Committee.

The repayment of Excess Compensation must be made by a Covered Executive notwithstanding any Covered Executive's belief (whether or not legitimate) that the Excess Compensation had been previously earned under applicable law and therefore is not subject to clawback.

In addition to its rights to recovery under the Policy, the Company or any affiliate of the Company may take any legal actions it determines appropriate to enforce a Covered Executive's obligations to the Company or to discipline a Covered Executive. Failure of a Covered Executive to comply with their obligations under the Policy may result in (without limitation) termination of that Covered Executive's employment, institution of civil proceedings, reporting of misconduct to appropriate governmental authorities, reduction of future compensation opportunities or change in role. The decision to take any actions described in the preceding sentence will not be subject to the approval of the Committee and can be made by the Board, any committee of the Board, or any duly authorized officer of the Company or of any applicable affiliate of the Company. For avoidance of doubt, any decisions of the Company or the Covered Executive's employer to discipline a Covered Executive or terminate the employment of a Covered Executive are independent of determinations under this Policy. For example, if a Covered Executive was involved in activities that led to an Accounting Restatement, the Company's decision as to whether to not to terminate such Covered Executive's employment would be made under its employment arrangements with such Covered Executive and the requirement to apply this no-fault and non-discretionary clawback policy will not be determinative of whether any such termination is for cause, although failure to comply with the Policy might be something that could result in a termination for cause depending on the terms of such arrangements.

Limited Exceptions to the Policy

The Company must recover the Excess Compensation in accordance with the Policy except to the limited extent that any of the conditions set forth below is met, and the Committee determines that recovery of the Excess Compensation would be impracticable:

- (a) The direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before reaching this conclusion, the Company must make a reasonable attempt to recover such Excess Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange;
- (b) Recovery would violate a law in the country where the Company was incorporated that was adopted prior to the date that the Policy was initially adopted. Before making this determination, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or
- (c) 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 legal requirements as such.

Other Important Information in the Policy

The Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer, as well as any other applicable laws, regulatory requirements, rules, or pursuant to the terms of any existing Company policy or agreement providing for the recovery of compensation.

Notwithstanding the terms of any of the Company's organizational documents (including, but not limited to, the Company's bylaws), any corporate policy or any contract (including, but not limited to, any indemnification agreement), neither the Company nor any affiliate of the Company will indemnify or provide advancement for any Covered Executive against any loss of Excess Compensation. Neither the Company nor any affiliate of the Company will pay for or reimburse insurance premiums for an insurance policy that covers potential recovery obligations. In the event that the Company is required to recover Excess Compensation pursuant to the Policy from a Covered Executive who is no longer an employee, the Company will be entitled to seek recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement that individual may have signed.

The Committee or Board may review and modify the Policy from time to time.

If any provision of the Policy or the application of any such provision to any Covered Executive is adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of the Policy or the application of such provision to another Covered Executive, and the invalid, illegal or unenforceable provisions will be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

The Policy will terminate and no longer be enforceable when the Company ceases to be listed issuer within the meaning of Section 10D of the Exchange Act.

ACKNOWLEDGEMENT

- I acknowledge that I have received and read the Compensation Recovery Policy (the “**Policy**”) of Ascentage Pharma Group International (the “**Company**”).
- I understand and acknowledge that the Policy applies to me, and all of my beneficiaries, heirs, executors, administrators or other legal representatives and that the Company’s right to recovery in order to comply with applicable law will apply, regardless of the terms of any release of claims or separation agreement I have signed or will sign in the future.
- I agree to be bound by and to comply with the Policy and understand that determinations of the Committee (as such term is used in the Policy) will be final and binding and will be given the maximum deference permitted by law.
- I understand and agree that my current indemnification rights, whether in an individual agreement or the Company’s organizational documents, exclude the right to be indemnified for amounts required to be recovered under the Policy.
- I understand that my failure to comply in all respects with the Policy is a basis for termination of my employment with the Company and any affiliate of the Company as well as any other appropriate discipline.
- I understand that neither the Policy, nor the application of the Policy to me, gives rise to a resignation for good reason (or similar concept) by me under any applicable employment agreement or arrangement.
- I acknowledge that if I have questions concerning the meaning or application of the Policy, it is my responsibility to seek guidance from the Legal Department, Human Resources or my own personal advisers.
- I acknowledge that neither this Acknowledgement nor the Policy is meant to constitute an employment contract.

Please review, sign and return this form to Human Resources.

Covered Executive

Dajun Yang
(print name)

/s/ Dajun Yang
(signature)

April 29, 2026
(date)
