**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 20-F**

**(Mark One)**

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

**OR**

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

**For the fiscal year ended March 31, 2025**

**OR**

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

**For the transition period from                to**

**OR**

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

Date of event requiring this shell company report

**For the transition period from                to**

**Commission file number: 001-41598**

**LakeShore Biopharma Co., Ltd**

(Exact name of Registrant as specified in its charter)

**N/A**

(Translation of Registrant’s name into English)

**Cayman Islands**

(Jurisdiction of incorporation or organization)

**Building No. 2, 38 Yongda Road**

**Daxing Biomedical Industry Park**

**Daxing District, Beijing, PRC, 102629**

**Tel: 010-89202086**

(Address of principal executive offices)

**Xu Wang, Director and Chief Executive Officer**

**Building No. 2, 38 Yongda Road**

**Daxing Biomedical Industry Park**

**Daxing District, Beijing, PRC, 102629**

**Tel: 010-89202086**

(Name, telephone, e-mail and/or facsimile number and address of company contact person)

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Title of Each Class** |  | **Trading Symbol** |  | **Name of Each Exchange on Which Registered** |
| **Ordinary share, par value US$0.0002 per share** |  | **LSB** |  | **Nasdaq Stock Market LLC** |
| **Warrants, each exercisable for one ordinary share** |  | **LSBPW** |  | **Nasdaq Stock Market LLC** |

**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.

As of March 31, 2025, there were 20,766,531 ordinary shares outstanding, par value US$0.0002.

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 ☒

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 “accelerated filer,” “large accelerated filer” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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 registration has used to prepare the financial statements included in this filing:

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

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 Section 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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| --- | --- | --- |
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**INTRODUCTION**

Unless otherwise indicated or the context otherwise requires in this annual report on Form 20-F (this “Annual Report”):

|  |  |  |
| --- | --- | --- |
|  | ● | “Articles” or “Articles of Association” means our second amended and restated memorandum and articles (as amended and restated from time to time), adopted on September 27, 2024 and effective from October 1, 2024; |

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| --- | --- | --- |
|  | ● | “Beijing Yisheng” means Beijing Yisheng Biotechnology Co., Ltd., a company incorporated under the laws of the PRC with limited liability and our wholly-owned subsidiary; |

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|  | ● | “Board” means our board of directors; |

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|  | ● | “Business Combination” means the transactions contemplated by the Business Combination Agreement which was consummated on March 16, 2023; |

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|  | ● | “Business Combination Agreement” means the business combination agreement, dated as of September 29, 2022, by and among LakeShore Biopharma, SPAC, Merger Sub I and Merger Sub II; |

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| --- | --- | --- |
|  | ● | “Cayman Companies Act” means the Companies Act (as Resed) of the Cayman Islands; |

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| --- | --- | --- |
|  | ● | “CDC(s)” means the Center(s) for Disease Control and Prevention; |

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|  | ● | “China” or “PRC” means the People’s Republic of China (and, only in the context of describing the industry matters, and the PRC laws, rules, regulations, regulatory authorities, and any PRC entities or citizens under such rules, laws and regulations and other legal, regulatory or tax matters and advice in this Annual Report, excludes Hong Kong, Macau and Taiwan). The term “Chinese” has a correlative meaning for the purpose of this Annual Report; |

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|  | ● | “Code” means the Internal Revenue Code of the 1986, as amended; |

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| --- | --- | --- |
|  | ● | “Company,” “LakeShore Biopharma,” “LakeShore Group,” “we,” “our,” “us,” or similar terms means LakeShore Biopharma Co., Ltd (formerly known as YS Biopharma Co., Ltd.), a company incorporated in the Cayman Islands with limited liability and, where the context requires, its consolidated subsidiaries from time to time; |

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|  | ● | “Exchange Act” means the U.S. Securities Exchange Act of 1934, as amended; |

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|  | ● | “GMP” means Good Manufacturing Practices; |

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|  | ● | “HK LakeShore Tech” means LakeShore Tech Hong Kong Limited, a company incorporated in Hong Kong with limited liability and our wholly-owned subsidiary; |

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|  | ● | “HK Yisheng” means YishengBio (Hong Kong) Holdings Limited, a company incorporated in Hong Kong with limited liability and our wholly-owned subsidiary; |

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|  | ● | “KOL(s)” means key opinion leaders; |

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|  | ● | “Liaoning Yisheng” means Liaoning Yisheng Biopharma Co., Ltd., a company incorporated in the PRC with limited liability and our wholly-owned subsidiary; |

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|  | ● | “Merger Sub I” means Oceanview Bioscience Acquisition Co., Ltd., a company incorporated in the Cayman Islands with limited liability, which was struck off as part of the Business Combination; |

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|  | ● | “Merger Sub II” means Hudson Biomedical Group Co., Ltd., a company incorporated in the Cayman Islands with limited liability and our wholly-owned subsidiary; |

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|  | ● | “Nasdaq” means the Nasdaq Stock Market LLC; |

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|  | ● | “NMPA” means the National Medical Products Administration in China; |

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|  | ● | “PCAOB” means the Public Company Accounting Oversight Board; |

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|  | ● | “Philippines Yisheng” means YS Biopharma (Philippines) Inc., a company incorporated in the Philippines with limited liability with limited liability and our wholly-owned subsidiary; |

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|  | ● | “PFIC” means a “passive foreign investment company” for U.S. federal income tax purposes; |

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|  | ● | “PRC government” means the governmental authorities of the PRC, including all political subdivisions (including central, provincial, municipal and other regional or local government entities) and its organs or, as the context requires, any of them; |

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|  | ● | “Sarbanes-Oxley Act” means the Sarbanes-Oxley Act of 2002, as amended; |

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| --- | --- | --- |
|  | ● | “SEC” means the U.S. Securities and Exchange Commission; |

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|  | ● | “Securities Act” means the Securities Act of 1933, as amended; |

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|  | ● | “Share(s)” or “ordinary share(s)” means ordinary share(s) in our capital with par value of US$0.0002 each; |

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| --- | --- | --- |
|  | ● | “Singapore LakeShore” means LakeShore Biopharma (Singapore) Pte. Ltd. (formerly known as Yisheng Biopharma (Singapore) Pte. Ltd.), a company incorporated in Singapore with limited liability and our wholly-owned subsidiary; |

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|  | ● | “SPAC” means Summit Healthcare Acquisition Corp., a company incorporated in the Cayman Islands with limited liability and our wholly-owned subsidiary; |

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|  | ● | “U.S. dollars,” “US$” or “$” means United States dollars, the legal currency of the United States; and |

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| --- | --- | --- |
|  | ● | “Warrant(s)” means warrant(s) to purchase Ordinary Share(s), with each whole warrant entitling the holder thereof to purchase one Ordinary Share. |

This Annual Report contains translations between Renminbi and U.S. dollars solely for the convenience of the reader. The translations from Renminbi to U.S. dollars and from U.S. dollars to Renminbi in this Annual Report were made at a rate of RMB7.1782 to US$1.00, the exchange rate set forth in the central parity rate release of the People’s Bank of China on March 31, 2025. We make no representation that the Renminbi or U.S. dollar amounts referred to in this Annual Report 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.

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**FORWARD-LOOKING STATEMENTS**

This Annual Report includes statements that express our opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results of operations or financial condition and therefore are, or may be deemed to be, “forward-looking statements.” These forward-looking statements can generally be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “seeks,” “projects,” “intends,” “plans,” “may,” “will” or “should” or, in each case, their negative or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs or current expectations concerning, among other things, results of operations, financial condition, liquidity, prospects, growth, strategies, future market conditions or economic performance and developments in the capital and credit markets and expected future financial performance, the markets in which we operate as well as any information concerning possible or our assumed future results of operations. Such forward-looking statements are based on available current market material and management’s expectations, beliefs and forecasts concerning future events impacting us. Factors that may impact such forward-looking statements include:

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| --- | --- | --- |
|  | ● | the regulatory environment and changes in laws, regulations or policies in the jurisdictions in which we operate; |

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| --- | --- | --- |
|  | ● | our ability to successfully compete in highly competitive industries and markets; |

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| --- | --- | --- |
|  | ● | our ability to continue to adjust our offerings to meet market demand, attract customers to choose our products and services and grow our ecosystem; |

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| --- | --- | --- |
|  | ● | political instability in the jurisdictions in which we operate; |

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| --- | --- | --- |
|  | ● | the overall economic environment and general market and economic conditions in the jurisdictions in which we operate; |

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| --- | --- | --- |
|  | ● | our ability to execute our strategies, manage growth and maintain our corporate culture as we grow; |

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| --- | --- | --- |
|  | ● | our anticipated investments in new products, services, collaboration arrangements, technologies and strategic acquisitions, and the effect of these investments on our results of operations; |

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| --- | --- | --- |
|  | ● | our ability to develop and protect intellectual property; |

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| --- | --- | --- |
|  | ● | changes in the need for capital and the availability of financing and capital to fund these needs; |

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|  | ● | anticipated technology trends and developments and our ability to address those trends and developments with our products and services; |

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| --- | --- | --- |
|  | ● | the safety, affordability, convenience and breadth of our products and services; |

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| --- | --- | --- |
|  | ● | man-made or natural disasters, health epidemics, and other outbreaks including war, acts of international or domestic terrorism, civil disturbances, occurrences of catastrophic events and acts of God such as floods, earthquakes, wildfires, typhoons and other adverse weather and natural conditions that affect our business or assets; |

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|  | ● | the loss of key personnel and the inability to replace such personnel on a timely basis or on acceptable terms; |

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| --- | --- | --- |
|  | ● | exchange rate fluctuations; |

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| --- | --- | --- |
|  | ● | changes in interest rates or rates of inflation; |

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| --- | --- | --- |
|  | ● | legal, regulatory and other proceedings; and |

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| --- | --- | --- |
|  | ● | our ability to maintain the listing of our securities on Nasdaq. |

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You should read this Annual Report and the documents that we refer to in this Annual Report thoroughly with the understanding that our future results may be materially different from and worse than what we expect. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in “Item 3. Key Information—D. Risk Factors,” “Item 4. Information on the Company—B. Business Overview,” “Item 5. Operating and Financial Review and Prospects,” and other sections in this Annual Report. You should read thoroughly this Annual Report and the documents that we refer to with the understanding that our future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report also contains statistical data and estimates we obtained from industry publications and reports generated by government or third-party providers of market intelligence. Although we have not independently verified the data, we believe the publications and reports are reliable. However, the statistical data and estimates in these publications and reports are based on a number of assumptions and if any one or more of the assumptions underlying the market data are later found to be incorrect, actual results may differ from the projections based on these assumptions. In addition, due to the rapidly evolving nature of the industry in which we operate, projections or estimates about our business and financial prospects involve significant risks and uncertainties.

The forward-looking statements made in this Annual Report relate only to events or information as of the date on which the statements are made in this Annual Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this Annual Report and the documents that we refer to in this Annual Report and exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect.

Before an investor makes an investment decision in our securities, it should be aware that the occurrence of the events described in “Item 3. Key Information—D. Risk Factors” and elsewhere in this Annual Report may adversely affect us.

**Explanatory Note**

Investing in our securities involves a high degree of risk. Please carefully consider the risks discussed under the section entitled “Item 3. Key Information—D. Risk Factors” in this Annual Report. We provide the following disclosure to help investors better understand our corporate structure, operations in China and the associated risks.

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**Holding Company Structure**

LakeShore Biopharma is not an operating company but a Cayman Islands holding company that conducts our operations in multiple countries, including China, Singapore, the Philippines and Cayman Islands, through our subsidiaries, including but not limited to, Beijing Yisheng, Liaoning Yisheng, Singapore LakeShore and Philippines LakeShore. Holders of our ordinary shares are not holding equity securities of our subsidiaries that have substantive business operations in China, Singapore and the Philippines, but instead are holding equity securities of a Cayman Islands holding company. The following diagram illustrates our corporate structure as of the date of this Annual Report.

A diagram of a diagram

AI-generated content may be incorrect.

**Our Operations in China**

We have substantial business and operations in China and thus are exposed to legal and operational risks associated with our operations in China. The PRC government has significant authority to exert influence on the ability of a company      with operations in China, including us, to conduct business. Changes in China’s economic, political or social conditions or government policies could materially and adversely affect our business and results of operations. Recent policy statements and regulatory actions by the PRC government, such as those related to human genetic data and biopharmaceutical and vaccine business, may adversely affect our ability to conduct our business and research and development (“R&D”) activities, accept foreign investments, or list on a U.S. or other foreign stock exchange, which may cause our securities to be prohibited from trading or to be delisted from the Nasdaq or any other U.S. stock exchange. Furthermore, the PRC government recently instituted more regulations to exert more oversight and control over overseas securities offerings and other capital markets activities and foreign investment in China-based companies. Any such action, once taken by the PRC government, could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless. For details, see “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China.”

**The Holding Foreign Companies Accountable Act and PCAOB’s Inspection over Financial Statements**

We are subject to a number of prohibitions, restrictions and potential delisting risk under the Holding Foreign Companies Accountable Act (the “HFCAA”). Pursuant to the HFCAA and related regulations, if we filed an audit report issued by a registered public accounting firm that the PCAOB determined is unable to inspect and investigate completely, the SEC will identify us as a “Commission-identified Issuer,” and the trading of our securities on any U.S. national securities exchanges, as well as any over-the-counter trading in the United States, will be prohibited if it is identified as a Commission-identified Issuer for two consecutive years. On December 16, 2021, the PCAOB issued a report to the SEC of its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong without the approval of the Chinese authorities, including our current auditor, Grant Thornton Zhitong Certified Public Accountants LLP. On August 26, 2022, the PCAOB signed a Statement of Protocol with the China Securities Regulatory Commission (the “CSRC”) and the Ministry of Finance of the PRC, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. On December 15, 2022, the PCAOB announced 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 determinations 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 conduct inspections of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong is subject to uncertainties and depends on a number of factors out of our and our auditor’s control. The PCAOB may continue to demand complete access in mainland China and Hong Kong, resume regular inspections and pursue ongoing investigations and initiate new investigations as needed. The PCAOB also indicated it will act immediately to consider the need to issue new determinations with the HFCAA if needed. We could still face the risk of delisting and cease of trading of our securities from a stock exchange or an over-the-counter market in the United States under the HFCAA and the securities regulations promulgated thereunder if the PCAOB is unable to inspect and investigate completely registered public accounting firms located in China in future years, or if we otherwise fail to meet the PCAOB’s requirements. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Our securities may be delisted under the Holding Foreign Companies Accountable Act if the PCAOB is unable to inspect auditors with presence in China in future years, and the delisting of our securities, or the threat of their being delisted, may materially and adversely affect the value of your investment.”

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**Cash and Asset Flows through Our Organization**

Cash is transferred among us, our offshore subsidiaries and our PRC subsidiaries, in the following manner: (1) funds are transferred to our PRC subsidiaries from us as needed through our subsidiaries outside China as capital contributions or shareholder loans, as the case may be; and (2) dividends or other distributions may be paid by our PRC subsidiaries to the Company through our subsidiaries outside China. Our subsidiaries in the PRC generate and retain cash generated from operating activities and re-invest it in our business. None of our subsidiaries outside China has made distributions to their respective shareholder(s). In the future, our ability to pay dividends, if any, to our shareholders and to service any debt we may incur will depend upon dividends paid by our subsidiaries. In the fiscal years ended March 31, 2023, 2024 and 2025, we did not transfer any cash to any of our PRC subsidiaries except for transfers in connection with the contribution of paid-in capital to our PRC subsidiaries, including the contribution of $1,008,768 by HK Yisheng to Beijing Yisheng’s paid-in capital during the fiscal year ended March 31, 2024. In the future, cash proceeds raised from overseas financing activities may be transferred by us through our subsidiaries outside China to our PRC subsidiaries via capital contribution and shareholder loans, as the case may be. Our PRC subsidiaries may pay dividends to our offshore subsidiaries to meet the capital needs of our business operations outside the PRC. For details about the PRC regulations and rules applicable to such cash transfers and the associated risks, see “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China.”

**Restrictions and Limitations on Transfer of Cash**

LakeShore Biopharma is incorporated in the Cayman Islands and its businesses in China are conducted through its PRC subsidiaries. We face various restrictions and limitations on foreign exchange, our ability to transfer cash between entities, across borders and to U.S. investors, and our ability to distribute earnings from our subsidiaries to LakeShore Biopharma and holders of ordinary shares.

Current PRC regulations permit our PRC subsidiaries, including Liaoning Yisheng, to pay dividends to us only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of their respective accumulated profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiaries may also allocate a portion of their after-tax profits based on PRC accounting standards to employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if Liaoning Yisheng incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other payments to us. Any limitation on the ability of our PRC subsidiaries, including Liaoning Yisheng, to distribute dividends to us may restrict our ability to satisfy our liquidity requirements. See “Item 4. Information on the Company—B. Business Overview—Regulation—Laws and Regulations in China—Regulations relating to foreign exchange and overseas investment.”

HK Yisheng, our wholly-owned subsidiary and the sole registered shareholder of Liaoning Yisheng, may be considered a non-resident enterprise for tax purposes, so that any dividends paid by our PRC subsidiaries, including Liaoning Yisheng, to HK Yisheng may be regarded as China-sourced income and, as a result, may be subject to PRC withholding tax at a rate of up to 10% to non-resident enterprise. If we are required under the PRC Enterprise Income Tax Law to pay income tax for any dividends we receive from PRC subsidiaries, or if HK Yisheng is determined by the PRC government authority as receiving benefits from reduced income tax rate due to a structure or arrangement that is primarily tax-driven, it would materially and adversely affect the amount of dividends, if any, we may pay to our shareholders. If the PRC tax authorities determine that LakeShore Biopharma is a PRC resident enterprise for enterprise income tax purposes, we may be required to withhold a 10% tax from dividends we pay to our shareholders, in each case that are non-resident enterprises. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Dividends payable to our foreign investors and gains on the sale of our securities by foreign investors may become subject to PRC tax.”

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In addition, non-resident enterprise shareholders, including holders of ordinary shares, may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of ordinary shares if such income is treated as sourced from within the PRC. Furthermore, if LakeShore Biopharma were deemed to be a PRC resident enterprise, dividends paid to our non-PRC individual shareholders, including holders of ordinary shares, and any gain realized on the transfer of ordinary shares by such holders may be subject to PRC tax at a rate of 20% which in the case of dividends may be withheld at source. Any such tax may reduce the returns on your investment in ordinary shares or ordinary shares. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law, and we may therefore be subject to PRC income tax on our global income.”

Our non-PRC entities are permitted under PRC laws and regulations to provide funding to our PRC subsidiaries only through loans or capital contributions, subject to the approval of government authorities and limits on the amount of capital contributions and loans. This may delay or prevent us from using the proceeds from our offshore capital raising activities to make loans or capital contribution to our PRC subsidiaries. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may restrict or delay us from using the offshore proceeds to make loans or additional capital contributions to our PRC subsidiaries, which could adversely affect our liquidity and ability to fund and expand our business.”

Additionally, the PRC government imposes controls on the convertibility of the Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Under existing PRC foreign exchange regulations, payments of current account items, such as trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from the State Administration of Foreign Exchange of the PRC, or the SAFE, by complying with certain procedural requirements. Dividends payments to us by HK Yisheng in foreign currencies are subject to the condition that the remittance of such dividends outside of the PRC complies with certain procedures under PRC foreign exchange regulations, such as the overseas investment registrations by our shareholders or the ultimate shareholders of our corporate shareholders who are PRC residents. Approvals by or registration with appropriate 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. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, our PRC subsidiaries, including the Liaoning Yisheng and Beijing Yisheng, may not be able to pay dividends in foreign currencies to us and our access to cash generated from its operations will be restricted. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Foreign exchange controls may limit our ability to effectively utilize our revenues and proceeds generated or financed outside China and adversely affect the value of your investment.”

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**Taxation on Dividends or Distributions**

LakeShore Biopharma’s source of dividend partly comes from dividends paid by its PRC subsidiaries, including Liaoning Yisheng. None of our subsidiaries has declared or paid any dividend or distribution to us as of the date of this Annual Report. We have never declared or paid any dividend on our ordinary shares, and we have no current intention to pay dividends to shareholders. We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. The undistributed earnings that are subject to dividend tax are expected to be indefinitely reinvested for the foreseeable future.

Under the current laws of the Cayman Islands, LakeShore Biopharma is not subject to tax on income or capital gains. Upon payments of dividends to our shareholders, no Cayman Islands withholding tax will be imposed. For purposes of illustration, the following discussion reflects the hypothetical taxes that might be required to be paid in China and Hong Kong, assuming that: (i) we have taxable earnings in our PRC subsidiaries, and (ii) we determine to pay a dividend in the future:

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| Hypothetical pre-tax earnings in the PRC subsidiaries(1) |  | 100.00 |  |
| Tax on earnings at statutory rate of 25% at PRC subsidiaries level(2) |  | (25.00 | ) |
| Amount to be distributed as dividend from the PRC subsidiaries to HK Yisheng(3) |  | 75.00 |  |
| Withholding tax at tax treaty rate of 5% |  | (3.75 | ) |
| Amount to be distributed as dividend at HK Yisheng level and net distribution to LakeShore Biopharma(4) |  | 71.25 |  |

Notes:

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|  | (1) | For purposes of this example, the tax calculation has been simplified. The hypothetical book pre-tax earnings amount is assumed to equal PRC taxable income. |

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|  | (2) | Liaoning Yisheng qualifies for a 15% preferential income tax rate in China. However, such rate is subject to qualification, is temporary in nature, and may not be available in a future period when distributions are paid. For purposes of this hypothetical example, the table above reflects a maximum tax scenario under which the full statutory rate would be effective. |

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|  | (3) | The PRC Enterprise Income Tax Law imposes a withholding income tax of 10% on dividends distributed by a Foreign Invested Enterprise to its immediate holding company outside of the PRC. A lower withholding income tax rate of 5% is applied if the Foreign Invested Enterprise’s immediate holding company is registered in Hong Kong or other jurisdictions that have a tax treaty arrangement with the PRC, subject to a qualification review at the time of the distribution. There is no incremental tax at HK Yisheng level for any dividend distribution to LakeShore Biopharma. |

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|  | (4) | If a 10% withholding income tax rate is imposed, the withholding tax will be 7.5 and the amount to be distributed as dividend at HK Yisheng level and net distribution to LakeShore Biopharma will be 67.5. |

ix

**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**

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|  | **A.** | **[Reserved]** |

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|  | **B.** | **Capitalization and Indebtedness** |

Not applicable.

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|  | **C.** | **Reasons for the Offer and Use of Proceeds** |

Not applicable.

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|  | **D.** | **Risk Factors** |

An investment in the ordinary shares involves significant risks. Below please find a summary of the principal risks we face, organized under relevant headings.

**Summary Risk Factors**

**Risks Related to Our Business and Products**

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|  | ● | We depend on our current marketed rabies vaccine product to generate substantially all of our revenue in the near term. Our previous operating history of manufacturing and commercializing vaccines may not provide an adequate basis to judge the viability of our business, the effectiveness of our management and our future profitability and prospects in respect of our marketed product. |

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|  | ● | We face substantial competition. Our competitors may discover, develop or commercialize products before, or more successfully than, we do, or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our marketed product and product candidates. |

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|  | ● | Our auditor has indicated that there is substantial doubt about our ability to continue as a going concern. |

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|  | ● | Our product candidates, once commercialized, may compete with our existing marketed product. |

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|  | ● | If the rabies vaccine industry in China does not grow as expected or declines, our ability to expand our business and results of operations could be materially and adversely affected. |

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|  | ● | The commercial success of any of our marketed product and product candidates depends on their degree of market acceptance by end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry. |

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|  | ● | The biopharmaceutical industry is highly regulated. The relevant regulations and policies are complex and regional and subject to changes from time to time. Our ability to obtain and maintain these regulatory approvals is uncertain. Any change in government regulation and policy may place additional burdens on our business and have a material adverse effect on our financial condition and results of operations. |

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|  | ● | Our marketed product and product candidates may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business. |

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|  | ● | We currently rely on the manufacturing facilities for the marketed product and are still developing additional facilities at other sites. Any disruption of our current and new facilities or their failure to meet GMP regulatory compliance or other regulatory requirements may have a material adverse effect on our business, financial condition and results of operations. |

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|  | ● | Failure to manage the normal manufacturing capacity properly may materially and adversely affect our revenues and profitability. |

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|  | ● | We have incurred significant losses since our inception. We might incur losses or fail to generate sufficient revenue to achieve satisfactory profitability in the future. |

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|  | ● | Our financial prospects depend on the sale of our marketed product, and the successful development and approval of our clinical-stage and preclinical stage product candidates. |

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|  | ● | We may need to obtain substantial additional financing to fund our operations, and a failure to obtain necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts. |

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|  | ● | The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain, and there can be no assurance that any of our technology, marketed product or product candidates will be protectable or remain protected by valid and enforceable patents. If we are unable to obtain and maintain patent protection for our marketed product and product candidates, or if the scope of such patent protection obtained is not sufficiently broad, third parties may compete directly against us. |

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|  | ● | While the lockdown in China ended, the aftereffect of the pandemic may continue to disrupt global economies and markets. We could be adversely affected by the ongoing global impacts and uncertainties of the COVID-19 pandemic or similar pandemics in the future. |

**Risks Related to Doing Business in China**

We face various legal and operational risks associated with doing business in China, which could cause the value of our securities to decline or become worthless, and significantly limit or completely hinder our ability to accept foreign investments and offer or continue to offer securities to foreign investors. These risks include, but are not limited to:

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|  | ● | We have a substantial business and operation in China and thus are exposed to legal and operational risks associated with our operations in China. The PRC government has significant authority to exert influence on the ability of a company with operations in China, including us, to conduct business. Changes in China’s economic, political or social conditions or government policies could materially and adversely affect our business and results of operations. For example, we face risks associated with regulatory approvals of offshore offerings, anti-monopoly regulatory actions, oversight on cybersecurity and data privacy, as well as the lack of PCAOB inspection on our auditors. On December 16, 2021, the PCAOB issued a report to the SEC of its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong without the approval of the Chinese authorities, including our current auditor, Grant Thornton Zhitong Certified Public Accountants LLP. On August 26, 2022, the PCAOB signed a Statement of Protocol with the CSRC and the Ministry of Finance of the PRC, taking the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong. On December 15, 2022, the PCAOB announced 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 determinations 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 conduct inspections of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong is subject to uncertainties and depends on a number of factors out of our and our auditor’s control. The PCAOB may continue to demand complete access in mainland China and Hong Kong, resume regular inspections and pursue ongoing investigations and initiate new investigations as needed. The PCAOB has also indicated it will act immediately to consider the need to issue new determinations with the HFCAA if needed. We could still face the risk of delisting and cease of trading of our securities from a stock exchange or an over-the-counter market in the United States under the HFCAA and the securities regulations promulgated thereunder if the PCAOB is unable to inspect and investigate completely registered public accounting firms located in China in future years, or if we otherwise fail to meet the PCAOB’s requirements. These China-related risks could result in a material change in our operations and/or the value of our securities, or could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or become worthless. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China.” |

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|  | ● | The PRC government has significant oversight and discretion over the conduct of our business and operations and may intervene with or influence our operations as the government deems appropriate to further regulatory, political and societal goals. Recent policy statements and regulatory actions by the PRC government, such as those related to human genetic data and biopharmaceutical and vaccine business, may adversely impact our ability to conduct our business and R&D activities, accept foreign investments, or list on a U.S. or other foreign stock exchange, which may cause our securities to be prohibited from trading or to be delisted from the Nasdaq or any other U.S. stock exchange. Furthermore, the PRC government recently instituted new regulations to exert more oversight and control over overseas securities offerings and other capital markets activities and foreign investment in China-based companies. Any such action, once taken by the PRC government, could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless. |

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|  | ● | The M&A Rules purport to require offshore special purpose vehicles that are controlled by PRC companies or individuals and that have been formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of PRC domestic companies or assets to obtain CSRC approval prior to publicly listing their securities on an overseas stock exchange. The interpretation and application of the M&A Rules remain unclear. There is no assurance, however, that regulators in China will not subsequently require us to undergo the approval or clearance procedures in relation to the Nasdaq listing and subject us to penalties for non-compliance. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Recent regulatory development in China may exert more oversight and control over listing and offerings that are conducted overseas. The approval, filing, and/or other requirements of PRC governmental authorities may be required under PRC laws, regulations or policies.” |

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|  | ● | On February 17, 2023, the CSRC issued the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (the “Trial Administrative Measures for Overseas Listing”) and five supporting guidelines, which came into effect on March 31, 2023. According to the Trial Administrative Measures for Overseas Listing and the CSRC press release regarding the Trial Administrative Measures for Overseas Listing published on its official website on February 17, 2023, an indirect overseas offering and listing by domestic companies, which refers to the offering and listing by a company by way of an overseas incorporated entity the major business operations of which are located domestically and such offering and listing is based on the underlying equity, assets, earnings or other similar rights of a domestic company, is subject to filing procedures with the CSRC. A company having been listed overseas before the effectiveness of the Trial Administrative Measures for Overseas Listing would only be subject to the filing requirements when conducting a follow-on offering of securities. However, given that the Trial Administrative Measures for Overseas Listing were recently promulgated, there remains substantial uncertainties as to their interpretation, application, and enforcement. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Recent regulatory development in China may exert more oversight and control over listing and offerings that are conducted overseas. The approval, filing, and/or other requirements of PRC governmental authorities may be required under PRC laws, regulations or policies” and “Item 4. Information on the Company—B. Business Overview—Regulations—Laws and Regulations in China—Regulations relating to overseas listing.” |

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**Risks Related to Ownership of the Ordinary Shares**

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|  | ● | We have been involved, and may continue to be involved, in claims, disputes, litigation, arbitration or other legal proceedings by or against Mr. Yi Zhang, the former chairperson of our board of directors and a principal shareholder of our Company. |

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|  | ● | The price of the ordinary shares may be volatile, and the value of the ordinary shares may continue to decline. |

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|  | ● | We are an emerging growth company and may take advantage of certain reduced reporting requirements. |

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|  | ● | 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. |

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|  | ● | Sales of the ordinary shares, or the perception of such sales, by us or the selling securityholders in the public market or otherwise could cause the market price for the ordinary shares to decline. |

**Risks Related to Our Business and Products**

**Risks Related to Our Marketed Product**

***We depend on our current marketed rabies vaccine product to generate substantially all of our revenue in the near term. Our previous operating history of manufacturing and commercializing vaccines may not provide an adequate basis to judge the viability of our business, the effectiveness of our management and our future profitability and prospects in respect of our marketed product.***

We currently own one marketed product in China, our YSJATM rabies vaccine, sales of which have generated and are expected to continue to generate substantially all of our revenue in the near term. In the fiscal years ended March 31, 2023, 2024 and 2025, revenues from sales of rabies vaccine accounted for approximately 100% of our total revenues. Our ability to continuously commercialize YSJATM rabies vaccine and expand our sales will depend on various factors, including, among other things, our ability to maintain proper manufacturing facilities, achieve effective sales and marketing, maintain competitive attractiveness, secure widespread acceptance of this product, maintain compliance with ongoing regulatory requirement, properly price and obtain coverage and adequate reimbursement of this product by governmental authorities, private health insurers and other third-party payors. If YSJATM rabies vaccine fails to achieve successful sales and further sales expansion, it could have a material adverse effect on our business, financial condition and results of operations.

The vaccine’s manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, recordkeeping, and post-marketing studies for our products are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with the Good Manufacturing Practice and the Good Clinical Practice. As of the date of this Annual Report, we manufacture YSJATM rabies vaccine in our GMP-compliant plant in Shenyang, China. If we intend to build new plants, or if the existing license for our current plant expires or is withdrawn, we will be required to apply for new license or renew our current license for future production, which may disrupt the production and commercialization plan of YSJATM rabies vaccine. In addition, each lot release of the rabies vaccine produced by us is subject to the inspection and pre-approval by relevant regulatory authorities before it enters into the market for sale. Any regulatory approvals we receive for our products are also subject to certain market limitations, approval conditions or post-market testing requirements. Any government investigation of alleged violations of relevant laws and regulations could generate negative publicity and subject us to additional compliance costs. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which may significantly harm our business, financial condition, results of operations and prospects.

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In addition, our previous operating history may not be indicative of our growth in business and revenue in the future. There may also be a decrease in demand, pricing or supply for our marketed product. Factors that could lead to such decline include, among others, increased competition, new product introductions, government-imposed pricing constraints, intellectual property issues, disruptions in manufacturing or distribution, and newly discovered safety issues. Any difference between our expected sales and the actual sales for our marketed product could materially and adversely affect our business, financial condition, results of operations and prospects.

***We face substantial competition. Our competitors may discover, develop or commercialize products before, or more successfully than, we do, or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our marketed product and product candidates.***

We face substantial competition with our marketed product, YSJA™ rabies vaccine, and product candidates, including PIKA rabies vaccine. Moreover, the development and commercialization of new products is also highly competitive. We face competition with respect to our existing product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Competitors of our product and product candidates include vaccines, cell-based immuno-oncology therapies, checkpoint inhibitors and other immunological biologics. Potential competitors also include academic institutions, government agencies and other public and private research organizations and companies that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacture and commercialization. Specifically, there are a large number of companies, including many major pharmaceutical and biotechnology companies, that develop or market treatments for infectious diseases and immuno-oncology drugs.

Many of the companies against which we are competing or 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 products than we do. 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 marketed product and product candidates. New competitors, domestic or foreign, may also enter into the markets in which we currently operate. Accordingly, we may not be able to outperform a competing product for any number of reasons, including:

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|  | ● | the competing product may be, or may be perceived to be, more effective, safer or otherwise superior in quality or brand recognition; |

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|  | ● | the competing product was introduced to the market earlier or gained wide market acceptance; |

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|  | ● | the competing product incorporates more recent technological innovations or research findings; |

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|  | ● | the competitor may have greater access to certain raw materials; |

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|  | ● | the competitor may have more efficient manufacturing processes, greater manufacturing capacity or lower manufacturing costs; |

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|  | ● | the competitors may develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more user-friendly or are less expensive; |

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|  | ● | the competitor may have stronger relationships or a more established history with regulatory bodies, and may obtain regulatory approval for their products more rapidly; |

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|  | ● | the competitor may have more aggressive marketing strategies, greater marketing capabilities or pricing flexibility; |

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|  | ● | the competing product might be protected by robust patent protections or enjoy market exclusivity; |

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|  | ● | the competitor might have more extensive distribution networks or strategic partnerships; or |

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|  | ● | the competitor may have established a stronger reputation and a higher degree of trust with customers, and may provide a more superior customer service and support. |

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The technologies used in our industry are evolving rapidly, and new developments frequently result in price competition and product obsolescence. Additionally, technologies developed by competitors may render our marketed product and product candidates uneconomical or obsolete, and we may not be successful in marketing our marketed product and product candidates against competitors. In addition, we may be impacted by competition from substitute products. If we are unable to compete effectively, we may lose market share and our financial performance may deteriorate. The availability of our competitors’ products could limit the demand and market share, the price we are able to charge, and the strategic opportunities for partnerships and collaborations for any products that we may develop and commercialize.

***Our auditor has indicated that there is a substantial doubt about our ability to continue as a going concern.***

To date, we had net loss for the year, accumulated deficits and cash used in operating activities. For the fiscal year ended March 31, 2025, we recorded net loss for the year of RMB100.0 million ($13.9 million) and net cash used in operating activities of RMB121.0 million ($16.9 million). As of March 31, 2025, we had an aggregate accumulated deficit of $335.4 million. As of March 31, 2025, we had cash of approximately RMB107.5 million (US$15.0 million), and outstanding loans and other borrowings of approximately RMB413.9 million ($57.7 million). In addition, we have been involved in certain legal proceedings in the Cayman Islands and arbitration claims in China against Mr. Yi Zhang, the former chairperson of the Board, and his associates. As a result of the net losses, the legal proceedings and other factors, our independent auditor issued an audit opinion with respect to our financial statements for the three years ended March 31, 2025 that indicated that there is a substantial doubt about our ability to continue as a going concern. Our financial statements have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These audited consolidated financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should we be unable to continue as a going concern.

There can be no assurance that we will ever be able to achieve or sustain profitability or positive cash flow. Our ability to continue as a going concern is dependent upon improving operational efficiency and cost reductions, generating sufficient cash flow from operations and obtaining additional capital and financing. If our ability to generate cash flow from operations is delayed or reduced and we are unable to raise additional funding from other sources, we may be unable to continue in business.

***Our product candidates, once commercialized, may compete with our existing marketed product.***

We are producing and selling YSJA™ rabies vaccine, which is a conventional rabies vaccine product. We are also developing PIKA rabies vaccine, which is a rabies vaccine featuring an accelerated regimen. Given the potential advantages of PIKA rabies vaccine over conventional products, we intend to formulate a premium pricing strategy to differentiate from conventional products, including YSJA™ rabies vaccine. Nevertheless, once PIKA rabies vaccine enters into the market, we may compete with YSJA™ rabies vaccine in, among others, customer acquisition, market position and commercialization resources, which may hinder the sales performance and growth of YSJA™ rabies vaccine. In addition, the growth potential and market position of PIKA rabies vaccines may also be affected by the presence and growth of YSJA™ rabies vaccine. The competition between our marketed product and any product candidate may also impose a burden on our internal resources, disrupt our cost structure and reduce our operating efficiency. As a result, our prospects and results of operations may be materially and adversely affected.

***If the rabies vaccine industry in China does not grow as expected or declines, our ability to expand our business and results of operations could be materially and adversely affected.***

The rabies vaccine industry in China has developed rapidly in the past decade, driven by favorable government policies, GDP growth, increase awareness on public health, affordability of vaccination and the emergence of new virus and pandemics, according to the Frost & Sullivan report. In 2024, a total of 12 companies produced and released approximately 81.7 million doses of human rabies virus vaccine in the Chinese Market, representing an increase of approximately 15.8 million doses, or 22.4%, compared to that of 2023. However, the continued growth of the rabies vaccine industry will depend on numerous factors, many of which are beyond our control, including but not limited to:

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|  | ● | development, safety and efficacy, availability and affordability of alternative therapeutics; |

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|  | ● | perception, recognition and acceptance of vaccines by end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry; |

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|  | ● | technological and scientific advancements, as well as manufacturing, storage and transportation techniques related to vaccines; |

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|  | ● | general awareness on public health; |

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|  | ● | changes in demographic composition and structure; |

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|  | ● | changes in the regulatory environment, government policy and utilization of resources on public health matters; |

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|  | ● | changes in insurance coverage of insurance companies and government programs; |

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|  | ● | the occurrence of global health crises; and |

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|  | ● | the general economic condition in China and globally. |

6

Any decline or slowdown in the growth of the vaccine industry could materially and adversely affect our ability to expand our business and generate positive operating results.

***The commercial success of any of our marketed product and product candidates depends on our degree of market acceptance by end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry.***

If end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry do not accept our marketed product or product candidates, we may be unable to generate significant revenue and may suffer losses. For example, in China, substantially all vaccine products are sold to CDCs, which comprise substantially our entire customer base for YSJA™ rabies vaccine. We cannot assure that our vaccine or vaccine candidates will gain market acceptance among CDCs in China. CDCs may reduce or cease the purchases if the patients do not accept these products or KOLs do not recommend our products. Failure to gain market acceptance would limit our ability to generate revenue as well as materially reduce our profitability.

In particular, CDCs and their physicians may elect not to recommend our products to patients for a variety of reasons, including the reimbursement policies of government and third-party payers, as well as the willingness of patients to pay out-of-pocket in the absence of such coverage reimbursement. There are other vaccines for the medical conditions that our marketed product and product candidates target. In order to successfully launch a product, CDCs’ physicians and patients must be educated about the relative benefits and advantages of our products over alternative products. If our products (including product candidates once commercialized) are not perceived to be user-friendly, present a lesser risk of side effects, or be more efficient or otherwise significantly better than other available products, our products may not be recommended or adopted by customers and end-users. A failure of our products to gain sufficient commercial acceptance would have a material adverse effect on our business, financial condition and results of operations. Even if our products 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 products, are more cost effective or render our products obsolete.

***If our marketed product and product candidates as well as the related manufacturing, storage, testing, delivery and other procedures do not meet the required quality standards, our business and reputation could be harmed, and our revenue and profitability could be materially and adversely affected.***

Our marketed product and product candidates as well as the related manufacturing, storage, testing, delivery and other procedures are required to meet certain quality standards to ensure product safety and efficacy. We cannot assure you that our quality control and assurance system can provide adequate and comprehensive protection against the associated risks at all times. Our quality control and assurance policies and procedures may suffer from design deficiencies or fail to account for all risks in the manufacturing, storage, testing, delivery and other procedures. In addition, our quality control and assurance personnel may fail to comprehend the related policies and procedures, or implement such in a stringent and consistent manner at all times. For example, we halted production of our marketed product for certain months in 2013 to address contamination issues. Moreover, we cannot eliminate the risk of all errors, defects or failure, whether they are attributable to us or third parties. Quality defects may be attributable to a number of reasons, including:

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|  | ● | manmade or naturally occurring errors and imprecision in the manufacturing, storage, testing, delivery and other procedures; |

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|  | ● | technical or mechanical malfunctions in the manufacturing, storage, testing, delivery and other procedures; |

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|  | ● | human error or malfeasance by our quality control, quality assurance, manufacturing, experiment and other personnel, as well as other responsible personnel of third parties; |

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|  | ● | tampering or interference by external entities or third parties; |

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|  | ● | use of outdated or poorly maintained equipment or technology; |

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|  | ● | insufficient or ineffective quality control systems; |

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|  | ● | non-compliance or negligence of regulatory guidelines by third-party collaborators, suppliers or vendors; |

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|  | ● | exposure to suboptimal manufacturing, storage, testing and delivery conditions or environment; and |

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|  | ● | quality issues with the raw materials and consumables we purchase or produce. |

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Failure to detect and cure quality defects in our vaccine products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license suspension or revocation, government investigations, legal actions, regulatory fines, increased cost, potential difficulties in future approvals, or negative media coverage that could damage our reputation and business, expose us to liability, and materially and adversely affect our revenue and profitability.

***Our business may be materially and adversely affected by product recalls or defects in the biopharmaceutical industry, and any other scandals and incidents that negatively affect the reputation and public perception of the vaccine industry as a whole.***

Both the manufacturing and distribution processes of biopharmaceutical products are complex. In addition, biopharmaceutical products must be stored properly to remain safe and effective. In the past, major biopharmaceutical companies had instances of product recalls due to product defects. Such recalls have in the past been subject to widespread media attention. Such recalls could damage both the reputation of major biopharmaceutical manufacturers, as well as the biopharmaceutical industry as a whole. In addition, there have been scandals of poor handling of production of biopharmaceutical products by certain companies. For example, in 2018, the Changchun Changsheng vaccine scandal in China caused widespread outrage where China’s second largest rabies vaccine manufacturer allegedly violated GMP manufacturing protocols and regulations, which resulted in the production of defective vaccines.

Such incidents have caused, and any future similar incidents and any negative publicity regarding the biopharmaceutical industry could cause, reputational damage to the biopharmaceutical industry and could reduce demand for biopharmaceutical products by creating negative public perception of vaccines. In addition, the government may promulgate new regulations and rules to reform, strengthen or change the existing supervision over the vaccine industry. If any of such event occurs, our business, financial condition and results of operations could be materially and adversely affected.

***Our marketed product and product candidates may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in disputes, claims, litigations or other significant negative consequences following any regulatory approval.***

Undesirable adverse events caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the National Medical Products Administration (the “NMPA”) in China, Health Sciences Authority (the “HSA”) in Singapore, U.S. Food and Drug Administration (the “FDA”) or other comparable regulatory authorities. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events, which could cause the suspension or termination of such trials, or the cessation of development and the denial of approval from relevant regulatory authorities. Undesirable adverse events caused by our products or product candidates may include but are not limited to, inflammatory response of certain organs. As most of our product candidates have not been testified in large-scale clinical trials, the adverse effect of such, especially that of long-term use, are uncertain. Certain types of disease may also not respond to our product candidates. In addition, combination therapy with other marketed products may cause uncertain adverse effect. Product-related adverse events could affect patient recruitment and the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Additionally, undesirable side effects or adverse events caused by or relating to our marketed product or product candidates may be discovered after they receive regulatory approval. Potential product liability is also a significant risk for biopharmaceutical companies, given that liability claims common in our industry are hard to foresee by nature. Such claims can also lead to product recalls, withdrawals, or declining sales, and/or be accompanied by consumer fraud claims by customers, third-party payers seeking reimbursement of the cost of the product and/or other claims, including potential civil or criminal governmental actions. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly.

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We have become, and may continue to become subject to such negative events and consequences, including but not limited to the following:

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|  | ● | we could be sued and held liable for adverse events to subjects in clinical trials or patients and the relevant compensation, regardless of whether a causal relationship can be proven; |

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|  | ● | we may suspend commercialization and marketing of the product; |

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|  | ● | regulatory authorities may withdraw approvals of the product; |

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|  | ● | we are subject to regulatory seizure of our products; |

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|  | ● | regulatory authorities may require additional warnings on the label; |

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|  | ● | we may be required to develop risk evaluation and mitigation strategies for the product, to incorporate additional requirements under such strategies, or to develop a similar strategy as required by a comparable regulatory authority; |

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|  | ● | we may be required to or propose by ourselves to conduct post-market studies; and |

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|  | ● | we could be prevented from achieving market acceptance of the particular product. |

***The recession or eradication of the infectious diseases that our vaccines target may adversely affect their sales.***

We devoted significant resources to the research and development of vaccines against infectious diseases and will continue to devote resources to the development of vaccines for novel infectious diseases. However, a pandemic or type of infectious disease may have receded before we realize any return on our investment in the research and development of our vaccines. Moreover, diseases that our vaccines target may be eradicated, which would eliminate the market of our vaccines. In addition, outbreaks of infectious diseases may cause CDCs to increase their purchases of vaccines against the pandemic diseases and reduce purchases of other vaccines in a short period. Changes of the procurement plans of CDCs could adversely affect sales of our vaccine products.

**Risks Related to the Development of Our Product Candidates**

***Our success depends substantially on the success of our product candidates in preclinical or clinical trial stages. Preclinical or clinical trials involve a lengthy and expensive process with uncertain outcomes. We may not be able to achieve our projected development goal of our product candidates in a timely manner or at all, which may materially and adversely affect our business, financial condition, results of operations and prospects.***

Our business success will substantially depend on the successful development, regulatory approval and commercialization of our product candidates, particularly our lead product candidates, such as simplified four-dose regimen for YSJATM, PIKA rabies vaccine and PIKA YS-ON-001. These product candidates are still in preclinical or clinical studies. Before we can generate revenue from sales of these product candidates, each of them will undergo preclinical and/or clinical studies, regulatory approval in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts. We invested a significant portion of our efforts and financial resources in the development of our existing lead product candidates, and will continue to evaluate the progress and prioritization of our product candidates and make further investment based on our evaluation, aligning with our financial condition, global health needs and market dynamics. The success of our product candidates will depend on several factors, including:

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|  | ● | successfully enrolling and/or completing preclinical studies and clinical trials, as well as other studies required to obtain regulatory approval; |

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|  | ● | obtaining regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or product registrations, manufacturing and commercialization; |

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|  | ● | establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers; |

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|  | ● | adequate fiscal support, technical proficiency and the ability to consistently obtain high-quality raw materials crucial to the implementation of preclinical studies, clinical trials, manufacturing processes, and commercialization; |

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|  | ● | relying on third parties to manage and conduct high-quality clinical trials safely and efficiently; |

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|  | ● | obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity; |

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|  | ● | ensuring that we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties; |

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|  | ● | commercializing our product candidates; |

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|  | ● | obtaining reimbursement from third-party payers for product candidates; |

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|  | ● | obtaining and maintaining healthcare coverage and adequate reimbursement; |

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|  | ● | competing with other products and product candidates in the market; |

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|  | ● | successfully enforcing and defending intellectual property rights and claims; and |

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|  | ● | achieving continued acceptable safety profile for our product candidates following regulatory approval. |

As a publicly listed company, we may continue to make such disclosures of our expectations in this respect. Notably, the progression of each product candidate is not only subject to its individual performance, but also our prioritization assessment and the relative advancement and potential of our entire portfolio. Thus, priority may be shifted between product candidates based on their comparative outlooks, which might impact the achievement of development milestones for individual candidates. The actual timing for achieving product development milestones could vary significantly from our expectations due to a number of factors, many of which are outside our control. There can be no assurance that our preclinical studies or clinical trials will be completed as planned or at all, or that we will make regulatory submissions or receive regulatory approvals as planned, or that we will be able to adhere to our current schedule for the launch of any of our products candidates. If we fail to achieve one or more of these milestones as planned, it could adversely affect the price of our Shares and our business prospects.

***Preclinical and clinical studies involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays, halts or failures in completing preclinical or clinical studies, or ultimately be unable to complete the development and commercialization of our product candidates.***

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical and clinical studies to demonstrate the safety and efficacy of our product candidates in non-human and human subjects. Clinical testing is expensive, difficult to implement, can take many years to complete, and is uncertain as to the outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and successful interim results of a clinical trial do not necessarily predict successful final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. We may nonetheless fail to obtain regulatory approval of our product candidates dependent solely on the discretion of each regulatory body.

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We may experience delays, halts or failures in completing our preclinical or clinical studies and numerous unforeseen events could arise during, or as a result of, future clinical trials, which could delay or prevent us from receiving regulatory approval of our product candidates. These factors include:

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|  | ● | regulators, institutional review boards (“IRBs”), or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site; |

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|  | ● | regulatory authorities may disagree with or change their position on the acceptability of our trial designs or clinical endpoints; |

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|  | ● | clinical trials may produce negative or inconclusive results, which could cause us to conduct additional clinical trials or abandon product development programs; |

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|  | ● | the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate; |

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|  | ● | third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; |

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|  | ● | clinical trial sites may withdraw from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; |

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|  | ● | we may fail to identify and maintain a sufficient number of trial sites; |

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|  | ● | the ability to conduct a companion diagnostic test to identify patients who are likely to benefit from our product candidates; |

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|  | ● | we may elect, or be required to, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks; |

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|  | ● | the cost of clinical trials of our product candidates may be greater than we anticipate, and we cannot obtain sufficient funds; |

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|  | ● | the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; |

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|  | ● | our product candidates may have undesirable side effects or unexpected characteristics, causing the termination of such trials, or reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates; |

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|  | ● | we may not complete preclinical or clinical trials as we originally scheduled; |

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|  | ● | we may encounter regulatory delays if a clinical trial is suspended or terminated due to various factors, including but not limited to a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, inspection of the clinical trial operations or trial site by regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial; and |

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|  | ● | our preclinical and clinical studies may be hindered, delayed or prevented by the occurrence or influence of other incidents or negative events, such as the long-term effects of COVID-19 and the ongoing global health situation, as well as political conflicts between China and other countries. |

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Many of these factors that cause a delay, halt or failure in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory approval of our product candidates and increases in product development costs. Significant preclinical study or clinical trial delays also could allow our competitors to acquire more market shares, which may harm our ability to commercialize our product candidates and adversely affect our business and results of operations.

***Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.***

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Future clinical trial results may not be favorable for a variety of reasons. For example, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the subject populations, including genetic and biological differences and other trial protocols. Various aspects of the development program, such as manufacturing and formulation, may be altered along the way in an effort to optimize processes and results. Such changes may not achieve these intended objectives or more compliance expenses. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of participants and resulting complexity due to the involvement of diversified demographics, as well as the large number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, which could require additional governmental communications and procedures for the altered clinical trial plan, delay the completion of clinical trials, delay approval of our product candidates and/or jeopardize our ability to commence commercialization of our product candidates.

***If the targeted market for our product candidates does not grow as expected or declines, our ability to expand our business and results of operations could be materially and adversely affected.***

The targeted markets for our product candidates, including, among others, the vaccine and infectious drug market in Southeast Asia and China are evolving, the continued growth of which will depend on numerous factors, many of which are beyond our control, including but not limited to:

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|  | ● | development, safety and efficacy, availability and affordability of alternative therapeutics; |

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|  | ● | perception, recognition and acceptance of vaccines by end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry; |

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|  | ● | technological and scientific advancements, as well as manufacturing, storage and transportation techniques related to vaccines; |

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|  | ● | general awareness on public health; |

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|  | ● | changes in demographic composition and structure; |

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|  | ● | changes in regulatory environment, government policy and utilization of resources on public health matters; |

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|  | ● | changes in insurance coverage of insurance companies and government programs; |

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|  | ● | the occurrence of global health crises; |

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|  | ● | the general economic condition in China and globally. |

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Any decline or slowdown in the growth of the vaccine industry could materially and adversely affect our ability to expand our business and generate positive operating results.

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

We intend to explore other biopharmaceutical opportunities in addition to our existing product candidates. However, we may fail to identify other product candidates for clinical trials for a number of reasons, such as research methodology challenges, harmful side effects, changes in market trends, lack of access to necessary raw materials, the emergence of competitive products or certain regulatory requirement. There can be no assurance that we will ever be able to identify additional biopharmaceutical opportunities for our product candidates or develop suitable potential product candidates.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may derive less value from that product candidate through collaboration, licensing or other royalty arrangements, as compared to retaining sole development and commercialization rights to such product candidate.

Because we have limited financial and managerial resources, we must limit our licensing, research and development programs to specific product candidates that we identify for specific indications. For example, we have focused on developing our PIKA immunomodulating technology platform, which we believe has great potential to create a wide variety of innovative immunological biologics to address underserved medical needs in treating and preventing infectious diseases and cancer. However, we may focus our efforts and resources on product candidates or other potential programs that ultimately prove to be unsuccessful or generate less return than expected, which may cause us to forego or delay pursuit of more successfully product development opportunities. Our resource allocation decisions may cause us to fail to capitalize on viable products or profitable market opportunities.

***We may rely on third parties to monitor, support and/or conduct preclinical or clinical trials of our product candidates. If the preclinical and clinical trial organizations do not perform in an acceptable manner, we may be unable to develop and commercialize our candidates as anticipated.***

We may rely on academic institutions, CROs, hospitals, clinics and other organizations and institutions, who are beyond our control, to monitor, support, conduct preclinical and/or clinical studies of our product candidates. As a result, we have less control over the quality, timing and cost of these studies and the ability to recruit trial subjects than if we conduct these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll subjects on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our future product candidates. If these third parties fail to meet expected deadlines, timely transfer to us any regulatory information, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or if they fail to comply with the confidentiality agreement, subcontract their obligations without our consent, or otherwise perform in a substandard manner or in a way that compromises the quality and/or accuracy of their activities and/or the data they obtain, then clinical trials of our future product candidates may be extended, delayed or terminated, or our data may be rejected by the NMPA, the HSA or other regulatory agencies.

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**Risks Related to Extensive Government Regulations**

***The biopharmaceutical industry is highly regulated. The relevant regulations and policies are complex and regional and subject to changes from time to time. Our ability to obtain and maintain these regulatory approvals is uncertain. Any change in government regulation and policy may place additional burdens on our business and have a material adverse effect on our financial condition and results of operations.***

The biopharmaceutical industry is subject to extensive government regulation and supervision, which addresses all aspects of operations in the biopharmaceutical industry, including but not limited to approval, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and certification requirements and procedures, periodic renewal and reassessment processes, registration of new drugs and environmental protection. For example, in order to manufacture and market any immunological biologics in China, a pharmaceutical company is required to obtain permits and certificates from the NMPA, including but not limited to the drug registration certificate (where applicable), the drug manufacturing license, and to pass the initial GMP inspections and continued compliance with the GMP, as well as other manufacturing requirements for our manufacturing facilities. The drug registration certificate and the drug manufacturing license are subject to renewal periodically. In addition, a vaccine manufacturer is also required to obtain lot release for each lot of vaccine products before they can be released to the market.

The lot release step involves the supervisory and administrative system by which the NMPA designates a drug inspection institution to conduct document review, on-site verification and sample inspection in connection with vaccine products, blood products, in vitro diagnostics for blood screening, or any other biological products as described by the NMPA, before any batch of such products can be marketed or exported. The NMPA updated certain standards in the National Pharmacopoeia for human rabies vaccines in late 2020. In order to comply with such new standards, we expect to spend more time to communicate with the competent authorities on the relevant testing methods and procedures before lot release approval.

Violation of applicable laws, rules and regulations by us may lead to our failure to obtain or renew permits, licenses or approvals required for operation in a timely manner or on commercially reasonable terms. As a result, we will not be able to engage in or have to suspend or cease the manufacture or sale of any products, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Our ability to manufacture our marketed product and our future approved product candidates depends on our ability to develop, validate and maintain commercially viable manufacturing processes that are compliant with GMP regulations. For example, we halted our production of marketed product for certain months in 2013 to address contamination issues. We cannot assure you we will be able to maintain required certificates or continue to meet the GMP requirements by the drug regulatory authority, which may cause us to suspend or terminate the manufacturing and commercialization of our marketed products, and materially and adversely affect our business, financial condition and results of operations.

The NMPA may also withdraw approval if compliance with regulatory requirements and standards are not maintained or if problems occur after our products reach the market. In addition, later discovery of previously unknown problems with our marketed product, including adverse events of unanticipated severity or frequency, or with our 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 (including but not limited to clinical studies) to assess new safety risks, or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation program. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. 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, regulatory requirements and approval process varies among countries, jurisdictions and regions, which may involve additional product testing and validation and additional administrative review periods. Our product candidates may need to apply for and obtain approval from multiple jurisdictions where we plan to study or market the products, which may be costly and time-consuming. Even if product candidates successfully complete clinical trials in one country, there is no assurance that clinical trials of the same product conducted with patients in other countries will be successful. Moreover, any safety issues, product recalls or other incidents related to products approved and marketed in one jurisdiction may impact approval of those products in another jurisdiction. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, or are imposed on certain product candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our product candidates or any other product candidate that we may in-license, acquire or develop in the future. The regulatory framework governing the biopharmaceutical industry is also subject to change and amendment from time to time. Any regulatory changes or amendment may materially and adversely impact our business, financial condition, results of operations and prospects.

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***Our marketed product and product candidates may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new immunological biologics vary widely from country to country. We might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in our marketed product and/or one or more product candidates, even if they obtain regulatory approval. For example, according to Opinions on Reforming the Review and Approval System for Pharmaceutical Products and Medical Devices, issued by the State Council in August 2015, the enterprises applying for drug approval in China will be required to undertake that the selling price of new drugs on the PRC market shall not be higher than the price of the product in the country of origin or the comparable market prices of the products in China’s neighboring markets, as applicable.

Our ability to commercialize any product successfully also depends in part on the extent to which reimbursement for such product and related treatments will be available from government health administration authorities, private health insurers and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which products and treatments they will cover and the amount of reimbursement, which is critical to the market acceptance of new products. There may be significant delays in obtaining reimbursement for approved product candidates, and coverage may be more limited than the purposes for which the product is approved by regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates and third-party payer coverage may be reduced for a number of commercial and regulatory reasons, all of which may adversely affect the commercialization of our marketed product or any product candidate.

As we intend to seek approval to market our marketed product and product candidates in multiple jurisdictions, we will be subject to various rules and regulations regarding coverage and reimbursement. Moreover, eligibility for reimbursement in China, Singapore or other jurisdictions does not imply that any product will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Moreover, in many jurisdictions, the pricing of products and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a product candidate. As a result, net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs, or private payers in the case of third-party reimbursement.

Our marketed product or product candidates may not be included in the list of products that can be reimbursed by mandatory medical insurance in China. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. The price of rabies vaccine in China also increases significantly. Patients may be unlikely to use certain of our marketed product and product candidates if coverage is not provided and reimbursement is inadequate to cover a significant portion of the cost of such marketed product and product candidates. Because some of our marketed product and product candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. In addition, our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any approved products could have a material adverse effect on our results of operations, our ability to raise capital needed to commercialize product candidates and our overall financial condition. Obtaining reimbursement for our marketed product may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. Therefore, the availability of third-party reimbursement may significantly impact the demand for, or the price of, any product for which we obtain regulatory approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize our marketed product or any product candidate that it successfully develops, which could have a material adverse effect on our results of operations, our ability to raise capital needed to commercialize product candidates and our financial condition.

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***We may not be able to be successfully prequalified by province-level CDCs of our target provinces or secure subsequent product orders.***

We expect the county-level CDCs, to be our primary customers in China. We are focused on China’s private vaccine market, and substantially all of our marketed product and product candidates are required to be prequalified by province-level CDCs of our target provinces through a bidding process before undertaking any sales. The province-level CDCs usually select one or more suppliers for the same type of vaccine, taking into consideration, among other things, the quality and price of the products and the service and reputation of the suppliers. We may be unsuccessful in winning bids in the tender process to prequalify our products at the provincial level. If we fail to obtain the required prequalification, we will lose market share to our competitors, and our revenue and profitability will be adversely affected. Even if our vaccines are prequalified, we cannot guarantee that we can maintain the standards and make continuous improvements to keep up with evolving market demands and regulations to achieve sustainability of the prequalification status, and neither can we guarantee our ability to secure purchase orders from county-level CDCs. If CDCs do not purchase our products, or the purchase volume is lower than expected, our business, financial conditions and results of operations would be adversely affected.

***Our sales to CDCs subject us to certain risks related to doing business with public authorities.***

We sell our vaccine products in China to CDCs and participate in public tenders hosted by them, which exposes us to certain risks related to doing business with public authorities. For example, although we sign contracts with them for sales of our vaccine products, and such contracts generally stipulate the payment time and method as well as dispute resolution, we have little or no control over their procurement decisions or payment cycles, and the CDCs that contract to purchase our products may reduce or cancel orders, or demand price adjustments or other changes to their contracts with us without our consent. Furthermore, we have experienced delays and may experience further delays in payments from these CDCs due to budget constraints, experienced by local governments in certain regions that led to slower payment settlement, and changes in governmental policies, which have impacted our cash flow and financial condition. Our participation and reliance on public tenders may also expose us to political changes and policy fluctuations, as the public health budget, regulatory guidelines, and the overall health care landscape may be influenced. For example, changes in the personnel of CDCs that purchase our products may result in changes or delays to, or cancellations of, their purchase commitments due to, among others, differing policy and budgetary agendas of the personnel involved. Furthermore, public tenders are typically highly competitive and governed by strict procurement regulations, which might lead to unpredictable outcomes and increased bidding costs. Any of the foregoing actions taken by the authorities could have a material adverse effect on our results of operations and expected earnings, or result in our failure to meet, or having to adjust downwards, our sales estimates.

In addition, many of the remedies that are available to us when dealing with private parties, such as making claims for breach of contract or taking other legal actions, may not be practicable in our dealings with CDCs. Our ability to seek legal remedies in instances of disputes with CDCs may be more limited than when interacting with private entities. For example, in the event of any dispute with a CDC, we may find pursuing formal legal action against a CDC might not be the most viable or beneficial strategy due to potential reputational harm or the risk of straining future relationships. It may be in our best interest to, instead, resolve such disputes through other means, such as negotiations or third-party mediation. However, it should be noted that the outcomes of these alternatives may not be as or more advantageous and favorable to us than those we would have obtained from traditional formal legal proceedings.

***We have been involved, and may continue to be involved, in claims, disputes, litigation, arbitration or other legal and administrative proceedings in the ordinary course of business.***

We have been involved, and may continue to be involved, in claims, disputes, litigation, arbitration or other legal and administrative proceedings in our ordinary course of business. We have been involved in legal proceedings in Cayman Islands against Mr. Yi Zhang, the former chairperson of the Board and his associates. We are also in arbitration proceedings in China with two entities controlled by Mr. Yi Zhang. See “Item 4. Information On the Company—Business Overview—Legal Proceedings and Compliance” for more details. These may concern issues relating to, among others, quality issues relating to our marketed product and product candidates, the manufacturing, storage, logistics and commercialization processes relating to our marketed product and product candidates, administrative actions, authority, procedures and decisions, product liability, environmental matters, breach of contract, construction projects, employment or labor disputes, and infringement of intellectual property rights.

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We are not involved in any ongoing litigation or legal proceedings that could materially and adversely affect the commercialization and research and development of our product and product candidates, or our business and results of operations. However, we cannot assure you that there will be no future disputes, litigation, arbitration, administrative investigation or other legal and administrative proceedings initiated by us or brought against us, with or without merit. We may involve additional administrative proceedings against us or initiated by us against the competent regulatory authorities to protect our legal rights and interests in the future. Any such claims, disputes or legal proceedings may result in substantial costs, disruption of our business operations, diversion of resources and material harm to our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to defective supplies sold to us by our suppliers, who may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

***We may not be able to manage our sales and marketing personnel effectively, and may consequently be subject to penalties pursuant to anti-corruption laws. Our reputation, business, prospects and brand may be materially and adversely affected by actions taken by them.***

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments, offering property or other illegal benefits to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policies and procedures designed to ensure that our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery. For example, although our company policies prohibit employees from making improper payments to CDCs or otherwise engaging in improper activities to influence the procurement decisions of drug products by CDCs, we may not be able to manage our sales and marketing employees effectively, as their compensation is primarily linked to their performance. Historically, certain former employees engaged in related misconduct and these former employees have been prosecuted. We have taken enhanced internal control measures, including setting up supervision group, reinforcing internal auditing efforts, and enhancing training and education on regular basis in respect of anti-corruption laws to our employees. We cannot assure you that these enhanced internal control measures will avoid the occurrence of similar events in the future or our employees will not violate the anti-bribery laws of China, the United States and other jurisdictions. Such violations could have a material adverse effect on our reputation, business, prospects and brand. Moreover, we could be liable for actions taken by these employees, including any violation of applicable laws in connection with the marketing or sales of products, such as China’s anti-corruption laws and the Foreign Corrupt Practices Act of the United States, or the FCPA. In particular, if employees make any payments that are forbidden under the FCPA, we could be subject to civil and criminal penalties imposed by the U.S. government. In addition, PRC laws regarding what types of payments to promote or sell products are impermissible in the pharmaceutical industry are not always clear. As a result, we, our employees or affiliates could make certain payments in connection with the promotion or sales of our products or other activities involving our products which at the time are considered by us to be legal but are later deemed impermissible by the PRC government. Any of the circumstances may materially and adversely affect our business, results of operations and financial condition.

Failure to comply with anti-bribery laws could disrupt our business and lead to criminal and civil penalties, including imprisonment, criminal and civil fines, loss of export licenses, and suspension of our qualification to do business with government authorities and CDCs. Other remedial measures may include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. Our reputation could be tarnished by any allegation or impropriety that we violated or may have violated such laws.

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***Product liability claims or lawsuits could cause us to incur substantial liabilities.***

We face an inherent risk of product liability exposure related to the use of our marketed product and the use of our product candidates in clinical trials or any product candidates. We have been and may in the future continue to be involved in product liability claims. Historically, we encountered certain civil and administrative proceedings in respect of our products. If we cannot successfully defend against claims that the use of such product or product candidates, including any of our product candidates that have received regulatory approval, caused injuries, we could incur substantial liabilities. We may be held liable and/or suffer reputation damage even if we are not at fault. Regardless of merit or eventual outcome, liability claims may result in:

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|  | ● | decreased demand for we marketed product and product candidates; |

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|  | ● | product recalls, withdrawals or labeling, marketing or promotional restrictions; |

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|  | ● | significant negative media attention and reputational damage; |

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|  | ● | withdrawal of clinical trial participants and inability to continue clinical trials; |

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|  | ● | hindered relationships with strategic partners, third party service providers, or regulatory authorities; |

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|  | ● | loss of existing or potential collaborations or contracts; |

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|  | ● | a negative impact on our ability to recruit and retain key personnel; |

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|  | ● | increased insurance premiums or inability to obtain insurance coverage; |

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|  | ● | significant costs to defend the related litigation; |

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|  | ● | substantial monetary awards to trial participants or patients; |

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|  | ● | inability to commercialize any product candidates that we may develop; |

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|  | ● | initiation of scrutiny investigations by regulators and authorities, leading to more stringent regulatory requirements; |

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|  | ● | a diversion of management’s time and our resources; and |

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|  | ● | a decline in our share price. |

The Vaccine Administration Law of the PRC (the “VAL”), which was promulgated on June 29, 2019 and came into effect on December 1, 2019, requires us to have compulsory liability insurance to cover vaccine product liability claims. The specific measures for implementing the compulsory liability insurance system for vaccines shall be formulated by the drug administrative department of the State Council in conjunction with the competent health department of the State Council and the insurance regulatory authority. To be implemented, the NMPA published a draft of the Administrative Measures on Vaccines Liability Compulsory Insurance for public comments in October 2020. To date, the draft has not become effective. Once passed, it will function jointly with the VAL to regulate the purchase of vaccines liability compulsory insurance, among others, including the liability limitation and methods for covering insurance. As these laws and regulations are relatively new and evolving, it is uncertain and in flux how the insurance companies and the governmental authorities will implement and carry out them in practice. We cannot assure you we will be fully compliant with these requirements, or that we will be able to enter into insurance agreements on commercially reasonable terms or at all, or that available insurance policies will fully cover our potential liabilities arising from our approved vaccines. As of the date of this Annual Report, we have maintained compulsory liability insurance for YSJA™ rabies vaccine in China. In addition, we maintain liability insurance for our ongoing clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury) in accordance with the relevant local laws and regulations where they are conducted. However, our insurance coverage may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with our collaborators.

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***We may be restricted from transferring our scientific data abroad and subject to regulations on human genetic resources.***

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (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. Although vast majority of the R&D projects have been funded by us since the inception of the Company, certain R&D projects were partially benefited from grants provided by Chinese governments. As of the date of this Annual Report, we have not provided any scientific data involving “state secret” in the course of foreign communication and cooperation, and therefore we believe that we do not need to obtain relevant permission and approvals pursuant to the Scientific Data Measures. Given the term “state secret” is not clearly defined in the Scientific Data Measures, we cannot assure you that we can always identify if there is any “state secret” in our scientific data and obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of product candidates may be hindered, which could materially adversely affect our business, financial condition, results of operations 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 rectification and other administrative penalties imposed by those government authorities.

According to the Regulation on the Management of Human Genetic Resources, as promulgated by the State Council on March 10, 2024, foreign organizations, foreign individuals and the institutions established or actually controlled thereby shall not collect or preserve China’s human genetic resources within the PRC, and shall not provide China’s human genetic resources abroad. Where a foreign organization or an institution established or actually controlled by a foreign organization or foreign individual needs to use China’s human genetic resources to conduct scientific research activities, it shall comply with the applicable laws, administrative regulations and relevant provisions in the PRC, and cooperate with China’s scientific research institutions, medical institutions and other enterprises provided therein. As of the date of this Annual Report, our current clinical trials in China, which involve PRC human genetic resources, are conducted in an international cooperation manner between us and PRC institutions and enterprises, and such cooperation has been approved by or filed with the competent authority. However, as uncertainties exist regarding the interpretation and implementation of these regulations, we cannot assure you we have been and will be fully in compliance with these regulations, including obtaining the filings or approvals in a timely manner or at all. Any failure to be compliant with these regulations may result in various penalties or other regulatory actions being imposed on us, such as confiscation of the revenues that were generated through the unauthorized activities, the imposition of fines, which could have an adverse effect on our business and results of operations.

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

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

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Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the patients’ private or medical records without their consent, they will be held liable for damage caused thereby. While we have taken measures to maintain the confidentiality of the medical records and personal data of patients enrolled in our clinical trials, these measures may not be always effective. Our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials also involve professionals from third-party institutions. We cannot ensure that such persons will always comply with our confidentiality agreements and data privacy measures. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure to protect the confidentiality of patients’ medical records and personal data, or any restriction on or liability as a result of our use of medical data, could have a material adverse effect on our business, financial condition, reputation and results of operations.

Moreover, regulatory authorities in China have implemented and are considering implementing a number of additional legislative and regulatory proposals concerning data protection. For instance, the PRC Cyber Security Law, which became effective in June 2017, created China’s first national-level information security classified protection system for “network operators,” which may include all entities in China that own, manage provide services or use over the internet or other information networks. The PRC Data Security Law was promulgated by the Standing Committee of the National People’s Congress ( the “SCNPC”) on June 10, 2021 and became effective on September 1, 2021. On July 7, 2022, the Cyberspace Administration of China published Outbound Data Transfer Security Assessment Measures, which became effective on September 1, 2022 and outlined the security assessment process for outbound data transfer. In addition, certain industry-specific laws and regulations may affect the collection and transfer of personal data in China, such as the Regulation on the Management of Human Genetic Resources. It is possible that these laws, regulations and guidelines may be interpreted and applied in a manner that is inconsistent with our practices, which could potentially result in confiscation of our human genetic resource samples and associated data and subject us to administrative fines, penalties and negative publicity.

***Our business operations are subject to the regulatory, economic, environmental, and competitive conditions and changes within the Southeast Asia region.***

We intend to expand our business and operations to overseas markets such as Southeast Asian countries, and thus may be governed by the laws, regulations and government policies in relevant Southeast Asia jurisdictions, and our business and future growth is dependent on the political, economic, regulatory and social conditions in these countries. There may also be political and social factors influencing government policy-making that will lead to a major shift towards a higher degree of governmental control over the biopharmaceutical industry in the relevant jurisdictions. Such a shift may reduce our profitability in the long run and hence have an adverse effect on our financial condition, results of operations and prospects. In particular, potential changes in import/export regulations, issues related to intellectual property protection, and potential barriers to entry in these new markets could impact our operations. In addition, competition laws and regulations of certain Southeast Asia countries may limit our growth and subject us to antitrust and merger control investigations. We may be subject to financial or other penalties or be prohibited from engaging in certain types of businesses or practices as a result of such investigations. We and our subsidiaries are governed by the laws, regulations and government policies in relevant Southeast Asia jurisdictions, and our business and future growth is dependent on the political, economic, regulatory and social conditions in these countries. Any material changes in the regulatory, economic, environmental or competitive conditions in those countries may also have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

***If we fail to comply with environmental, health and safety laws and regulations of the PRC, 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 are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory and manufacturing procedures and the handling, use, storage, discharge, treatment and disposal of hazardous materials, sewage and wastes. Our operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce hazardous products and waste. Therefore, we are subject to PRC laws and regulations concerning the discharge of hazardous materials, wastewater, gaseous waste and solid waste during our research and development of products. We engaged competent third-party contractors for the transfer and disposal of these materials and wastes. However, we may not guarantee you that we, at all times, have complied or would comply fully with relevant regulations. Any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligation to take corrective measures.

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We cannot assure you of the elimination of the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or our or third parties’ disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources.

Although we maintain workers’ compensation insurance to cover costs and expenses incurred from on-the-job injuries to our employees and third-party liability insurance for injuries caused by unexpected seepage, pollution or contamination, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the PRC government may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our manufacturing facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations.

***The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our marketed product and product candidates.***

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs and vaccines and their development. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that we 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 product and product candidates in China and reduce the current benefits we believe are available to us from development and manufacturing in China. In addition, the interpretation and enforcement of these laws and regulations involve significant uncertainty and the possible introduction of new laws or changes to existing laws pose potential risks. 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, permits and filings may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the Chinese government’s policies in all material respects, but we cannot ensure that our strategy and approach will continue to be aligned.

**Risks Related to Manufacturing and Commercialization**

***We currently rely on the manufacturing facilities for the marketed product and are still in the process of developing additional facilities at other sites. Any disruption of our current and new facilities or their failure to meet GMP regulatory compliance or other regulatory requirements may have a material adverse effect on our business, financial condition and results of operations.***

There are some manufacturing plants in Shenyang, China, which are currently producing our marketed product and clinical samples. We plan to expand or upgrade productivity based on our current manufacture site in Shenyang for manufacturing our marketed product and product candidates in the future. Upon completion of the manufacturing process, we first store the finished goods of our vaccine products in our Shenyang facilities, which are then shipped to our regional facilities for temporary transit storage before subsequent delivery. We do not maintain back-up facilities and depend on current facilities for the continued operation of our business. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortage, storms, fires, earthquakes, terrorist attacks and wars, as well as changes in governmental planning for the land underlying these facilities, could significantly impair our ability to manufacture products and operate business and destroy any inventory located in those facilities. The occurrence of such an event could significantly disrupt our business and materially reduce our revenues and profitability.

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In addition, we are required to comply with applicable GMP and other regulatory requirements, including regulatory standards with respect to manufacturing process or product quality and safety, cold-chain logistics during product delivery, and the corresponding maintenance, recordkeeping and documentation standards. Our manufacturing facilities must be approved by governmental authorities before we may use them to commercially manufacture products and are subject to inspection by regulatory agencies. Moreover, our marketed product must pass quality inspection prior to being permitted to hit the market for sale. Any changes in or updates to the GMP standards could impose higher or different regulatory requirements on our manufacturing, such as the manufacturing process, standard, technology, personnel and facilities, and we cannot assure you that we will be able to meet the regulatory changes in a timely manner or at all, which could materially and adversely affect our business operations, results of operations, reputation and prospects. We are also responsible for maintaining effective cold-chain logistics during the vaccine transportation process to the county-level CDCs. If we fail to comply with applicable regulatory requirements at any stage during the manufacturing and transportation process, such as, regulatory standards with respect to manufacturing and transportation processes or product quality, safety and potency, we may be subject to sanctions which could be severe, including but not limited to:

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|  | ● | monetary penalties; |

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|  | ● | product recalls or seizure; |

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|  | ● | injunctions; |

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|  | ● | refusal of regulatory agencies to review pending manufacturing approval applications or supplements to approval applications; |

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|  | ● | total or partial suspension of production; |

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|  | ● | confiscation of products; |

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|  | ● | withdrawals, revocation or non-renewal of approvals, license or permits previously issued; and |

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|  | ● | criminal prosecution. |

Any disruptions or delays at our facilities or their failure to meet GMP regulatory compliance or other regulatory requirements would also impair our ability to develop and commercialize our product and product candidates, which would adversely affect our business and results of operations.

***Real or perceived incidents of product contamination caused by our marketed product could materially and adversely affect our reputation, results of operations and financial conditions, and subject us to regulatory actions and contractual liabilities.***

Product safety and quality is critical to our business. For example, our production was halted for certain months in 2013 to address contamination issues. We cannot assure you we will not encounter similar incidents in the future. Our reputation, results of operations and financial condition could be materially and adversely affected by product contamination and our association with any contamination incidents. In addition, the mere publication of information or speculation asserting that our marketed product contains or has contained any contaminants, over which we have no control, could damage our reputation and have a material adverse effect on us, regardless of whether such information or speculation have any factual basis. We may be exposed to a number of harmful consequences due to product contamination, including:

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|  | ● | injury or death of patients; |

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|  | ● | severe decrease in the demand for, and sales of, the relevant products; |

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|  | ● | recall or withdrawal of the relevant products; |

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|  | ● | revocation of regulatory approvals for the relevant products or the relevant production facilities; |

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|  | ● | damage to the brand name of our marketed product and our reputation; |

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|  | ● | stricter and more frequent regulatory inspections of our manufacturing facilities and products; |

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|  | ● | inability to participate in the centralized tender process; |

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|  | ● | delays or disruptions in our ability to develop new products or expand into new markets; |

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|  | ● | exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties; and |

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|  | ● | breach of contract with our major customers and business partners. |

***Failure to manage the normal manufacturing capacity properly may materially and adversely affect our revenues and profitability.***

The normal manufacturing capacity is calculated based on the designed capacity of our manufacturing facilities, after taking into account any reduction in capacity caused by, among other factors, suspension of manufacturing for renewal of GMP certification, if required, maintenance or expansion. The normal manufacturing capacity for a product directly determines the maximum amount of immunological biologics that could be produced in a given period and the volume of finished products that will be available for sale in subsequent periods.

Proper management of the normal manufacturing capacity, and in particular, minimizing the time for renewing GMP certification, if required, and maintaining GMP-compliant conditions and sufficient GMP-compliant back-up capacity in preparation for suspension of manufacturing caused by planned or unexpected events, is critical to maintaining a steady supply of products and a stable growth in our revenues. In addition, if the normal manufacturing capacity is substantially lower than the designed capacity, idle production costs, a major component of our cost of sales, may increase significantly.

Given the uncertainties inherent in the biopharmaceutical industry, we have been actively taking measures to improve the management of the normal manufacturing capacity, including building new manufacturing facilities. Our contingency planning also includes measures to mitigate the impact of reduced manufacturing capacity, such as adoption of production process and installation of instruments or equipment which are common and versatile for multiple product uses in the future. However, we cannot assure that such measures will be successful. The failure of such measures may significantly reduce products available for sale in subsequent periods and/or increase the idle costs, materially and adversely affecting our revenues and profitability.

***If we are unable to conduct effective sales and marketing, our business, financial condition, results of operations and prospects could be adversely affected.***

Successful sales and marketing are crucial for us to increase the market penetration and sales of our marketed product and expand our market coverage. If we fail to attract, motivate and retain qualified commercialization team members and maintain an effective system to manage our commercialization team, or if our commercialization team underperforms, we may experience disruptions to our business, declines in sales volume and less favorable market penetration, and fail to compete effectively. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, our sales volumes, geographic coverage and business prospects could also be adversely affected. In addition, our sales and marketing efforts depend in part on the functions of our external service providers. While we implement systematic measures to manage our external service providers, such engagement may expose us to certain risks, including: (1) failure to collect receivables on a timely basis or effectively; (2) failure to possess, maintain or develop the resources and capabilities required as a service provider; (3) failure to retain or attract high or capable performing service providers; (4) failure to maintain or renew relevant qualifications; (5) engaging in non-compliant conducts, especially in those areas out of our direct supervision; (6) failure to protect our proprietary information and intellectual properties despite of the contractual obligation; and (7) failure to report adverse events or side effects, or process potential recalls in a timely manner. Any of these incidents may have an adverse impact on our business and results of operations.

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***Failure to establish a complete and effective network of cold-chain logistics providers or otherwise maintain effective and comprehensive cold-chain logistics during transportation of our vaccine products may cause great risk of damage to our vaccine products and our reputation and business would suffer.***

Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and others to light. Vaccine manufacturers are required to sell directly to county-level CDCs and take charge of quality control during transportation until the products are delivered to the county-level CDCs. Furthermore, the vaccines must be transported through a cold-chain within the temperature range provided by relevant requirements. To ensure our compliance with relevant laws and regulations and maintain product quality and potency, our vaccines must be stored in good conditions through cold-chain logistics providers. In order to maintain a reliable vaccine cold chain at manufacture level before delivery to our customers, we are required to, among others, establish a complete and effective network of cold-chain logistics providers to store vaccines and diluents within the approved temperature range at all sites, pack and transport vaccines to and from outreach sites according to recommended procedures, and perform regular oversight and monitor on the delivery process to our customers, or other safety, efficacy and quality issues. We were involved and may in the future be involved in certain administrative proceedings concerning the temperature conditions during the testing and transportation by third parties for our marketed product, which might have affected the testing results and resulted in negative implications for our product quality and reputation. If we or third parties we cooperated with fail to comply with cold-chain logistics during transportation, such as during the delivery process to customers and the inspection process, our vaccine products may be exposed to inappropriate temperatures or other improper storage conditions and subject to potency diminishment or even potency loss. In this case, all the vaccine products are subject to quality damage and may need to be destroyed. As a result, our reputation and business would suffer. We may also be exposed to third-party risks with respect to the cold-chain logistics concerning our entire commercialization process, some of which are beyond our control.

***Counterfeits of our products and illegal vaccines could negatively affect our sales and our reputation and expose us to liability claims.***

Certain vaccines distributed or sold may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit vaccine products. The counterfeit vaccine product control and enforcement system, particularly in developing markets might be inadequate to discourage or eliminate the manufacturing and sale of counterfeit vaccine products imitating our products. Since counterfeit vaccine products in many cases have very similar appearances with the authentic vaccine products but are generally sold at lower prices, counterfeits of our products can quickly erode our sales volume of the relevant products. Moreover, counterfeit products may or may not have the same chemical composition as our products do, which may make them less effective than our products, entirely ineffective or more likely to cause severe adverse side effects. Despite our best efforts, we may not be able to entirely prevent or address such issues due to limitations in regulation enforcement or tracking technologies. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. The existence and prevalence of counterfeit vaccine products, products of inferior quality and other unqualified products in recent years from time to time may reinforce the negative image in general of all pharmaceutical products manufactured in China among consumers, and may harm the reputation of companies like us.

***Failure to maintain and predict inventory levels in line with demand for our marketed product could cause us to lose sales or face excess inventory risks and holding costs, which could have a material adverse effect on our business, financial condition and results of operations.***

We maintain an inventory level based on anticipated product demand and production schedule. However, we cannot guarantee that we will be able to maintain proper inventory levels for marketed product and raw materials. Inventory levels in excess of product demand may result in inventory write-downs, expiration of products and increase in inventory holding costs. Conversely, we may experience inventory shortages if we underestimate demand for our products, which may result in unfilled orders and have a negative impact on our relationship with our customers. To manage our inventory level, we have implemented certain measures. See “Item 4. Information on the Company—B. Business Overview—Inventory Management.” However, we cannot assure you that these measures will be effective and our inventory level will decrease in the future. If our inventory level increases further in the future, our financial condition and cash flow could be materially and adversely affected.

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***Our business depends on the use of raw materials, and a decrease in the supply or an increase in the cost of these raw materials could materially and adversely affect our business, financial condition and results of operations.***

To manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. Any disruption in production or inability of or suppliers to produce and provide adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our future product candidates. Moreover, we expect our demand for such materials to increase as we expand our business scale and commercialize our products, and we cannot guarantee that current suppliers have the capacity to meet our demand. We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. Recently, as a result of intensified trade tensions between China and the United States, including tariffs, export controls and other international measures, the cost of imported raw materials, consumables and equipment have increased. Consequently, we may face higher procedure costs. In addition, we currently largely rely on a single supplier for several key raw materials, which increases the risk of supply disruptions. Although we are seeking alternative suppliers, switching or adding new suppliers can be costly and time-consuming, and we cannot guarantee that new suppliers will meet our requirements. Any significant disruption or increase in costs related to our supply chain could negatively impact our business and financial results.

In addition, we might need to import certain raw materials from overseas suppliers, which might subject us and our overseas suppliers to compliance cost with respect to import and export regulations and relevant inspection and quarantine requirements. In addition, although we have implemented quality inspection procedures on such materials before they are used in our manufacturing processes and required our suppliers to maintain high quality standards, we cannot guarantee that we will be able to secure sufficient quantities of raw materials at high quality standards, nor detect all quality issues in the supplies we use. We cannot assure you that these third parties or itself will be able to maintain and renew all filings, licenses, permits and approvals necessary for their operations, supply of raw materials or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the supplies to us. If we are unable to do so and the quality of our products suffer as a result, we may have to delay market supply, clinical trials and regulatory filings, recall our products, be subject to product liability claims, fail to comply with continuing regulatory requirements and incur significant costs to rectify such issue, which may have a material and adverse effect on our business, financial condition and results of operations.

***We deal with potentially harmful biological materials and other hazardous materials that may cause environmental contamination or injury to others.***

Our research and development programs, clinical trials and manufacturing operations involve the controlled use of potentially harmful biological materials and other hazardous materials, such as pathogenic microbe. We are required to obtain and timely renew relevant approvals, permits and filings in the course of our development and manufacturing activities while we might face challenges or delays or failures in obtaining or renewing these approvals, permits and filings due to unforeseen circumstances or changes in regulatory environments. In particular, the risk of accidental contamination to the environment or injury to our employees or others from the use, manufacture, storage, handling or disposal of these materials may not be completely eliminated. In the event of contamination or injury, we could be held liable for any resulting damages, which could exceed our resources or any applicable insurance coverage they may have. Furthermore, governmental agencies could initiate investigations against us, which may result in fines, sanctions, revocations of operating permits, suspension of their operations, closure of our facilities or other penalties. Our reputation may be harmed as well. Furthermore, laws, rules or regulations regarding handling of harmful biological materials and other hazardous materials, or more stringent environmental regulations that may be adopted in the future, may mandate additional protective and other measures against potential contamination or injury caused by these materials, compliance with which could be costly, and our profitability could be materially reduced as a result.

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**Risks Related to Our Financial Position and Working Capital Need**

***We have incurred significant losses since our inception. We might incur losses or fail to generate sufficient revenue to achieve satisfactory profitability in the future.***

We have incurred, and expect to continue to incur, significant expenses related to clinical trials and preclinical studies in the future. As of the date of this Annual Report, we have one marketed product, YSJA™ rabies vaccine, and we have begun to recognize revenue from sales of YSJA™ rabies vaccine since October 2020. We had net loss of RMB145.5 million, RMB433.5 million and RMB100.0 million ($13.9 million) for the fiscal years ended March 31, 2023, 2024 and 2025, respectively. Our future financial position will depend, in part, on the sale of our marketed product, the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. Our future revenue and profitability will also depend upon the size of any markets in which our product and product candidates have received approval, the commercialization of our product candidates, our manufacturing capabilities, our ability to achieve sufficient market acceptance, secure procurement from CDCs in China and other factors. We expect to continue to incur significant expenses and operating losses in the foreseeable future. We anticipate that our expenses will increase if and as it:

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|  | ● | experiences the sales growth of YSJA™ rabies vaccine; |

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|  | ● | continues to advance the clinical trials and preclinical studies of our current pipelines; |

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|  | ● | initiates preclinical, clinical or other studies for new product candidates; |

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|  | ● | manufactures materials for clinical trials and for commercial sale; |

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|  | ● | seeks regulatory approvals for our product candidates that successfully complete clinical trials; |

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|  | ● | develops and expands our commercialization team to promote the sale of our marketed product and commercialize any products for which we may obtain marketing approval; |

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|  | ● | acquires or in-licenses other product candidates and technologies; |

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|  | ● | maintains, protects and expands our intellectual property portfolio and compliance system; |

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|  | ● | attracts and retains skilled personnel; and |

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|  | ● | creates or adopts additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts. |

Our ability to become and remain profitable depends on our ability to generate sufficient revenue. Even if we are able to generate revenue from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce our operations. our failure to become and remain profitable would decrease the value of us and could impair our ability to raise capital, expand our business or continue our operations. Failure to become and remain profitable may adversely affect the market price of our Shares. A decline in our value could also cause you to lose all or part of your investment.

***Our financial prospects depend on the sale of our marketed product, and the successful development and approval of our clinical-stage and preclinical stage product candidates.***

Our ability to generate revenue and become profitable depends upon our ability to achieve sales growth of YSJA™ rabies vaccine and to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. We expect sales of YSJA™ rabies vaccine to generate substantially all of our revenue in the near term. Our ability to successfully commercialize YSJA™ rabies vaccine and expand our sales will depend on, among other things, our ability to maintain proper manufacturing facilities, achieve effective sales and marketing, maintain competitive attractiveness, secure widespread acceptance of this product, maintain compliance with ongoing regulatory requirement, properly price and obtain coverage and adequate reimbursement of this product by governmental authorities, private health insurers and other third-party payors. If YSJA™ rabies vaccine fails to achieve successful sales and further sales expansion, it could have a material adverse effect on our business, financial condition and results of operations.

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We are also developing multiple product candidates for infectious diseases and cancer. We have invested a significant portion of our efforts and financial resources in the development of our product candidates, and we expect to continue to incur substantial and increasing expenditures through the projected commercialization of these product candidates. None of these product candidates has been approved for marketing in China or any other jurisdiction and may never receive such approval. Our ability to achieve revenue and profitability is dependent on our ability to expand the sales of YSJA™ rabies vaccine and complete the development of product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed.

Moreover, because we have limited financial and managerial resources, we focus our product pipelines on research and development programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial productor profitable market opportunities. Our spending on current and future research and development programs and product 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 product candidate, we may relinquish valuable rights to that product 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.

***We may need to obtain substantial additional financing to fund our operations, and a failure to obtain necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.***

In the three fiscal years ended March 31, 2025, we primarily funded our operations through investments from investors, bank borrowings, proceeds from Business Combination and cash from sales of our marketed rabies vaccines. We believe we will need to spend substantial resources for the commercialization and sales of our marketed product and the research and development and commercialization of our product candidates. Our future capital requirements depend on many factors, including:

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|  | ● | the commercialization and sale of our marketed product and the cost and timing of future commercialization activities for our marketed product and our product candidates, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs; |

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|  | ● | the commercialization and sales of our product candidates at discovery and clinical stage; |

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|  | ● | the progress, results and costs of the clinical, preclinical and other studies of our product candidates; |

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|  | ● | the timing, receipt, and amount of sales of, or royalties or milestone payments on, our future products, if any; |

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|  | ● | discovery of new product candidates; |

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|  | ● | the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates; |

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|  | ● | the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation; and |

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|  | ● | the extent to which we acquire or in-license other products or technologies. |

We plan to use the outstanding cash, together with bank borrowings and cash from operating activities, to primarily fund our future operations. However, if the commercialization of our marketed product and product candidates is delayed or terminated, or if expenses increase, we may need additional financing to fund our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control.

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As of March 31, 2025, LakeShore Group had 10,750,000 public warrants and 6,000,000 private warrants outstanding. LakeShore Biopharma completed a 1-for-10 reverse split in October 2024, and each warrant became exercisable for 0.1 share of common stock. Our ability to obtain additional financing from the exercise of such Warrants may be limited. There is no assurance the holders of the Warrants will elect to exercise any of the Warrants, which could impact our liquidity position. Whether holders of Warrants will exercise their Warrants, and therefore the amount of cash proceeds we would receive upon exercise, is dependent upon the trading price of the ordinary shares. Each Warrant is exercisable for 0.1 ordinary share at $11.5. Therefore, if and when the trading price of the ordinary shares is less than $115.0 per share, we expect that holders of Warrants would not have the financial incentive to exercise their Warrants. We could receive up to an approximately $192.6 million if all of the Warrants are exercised for cash, but we would only receive such proceeds if and when the holders of Warrants exercise the Warrants. The Warrants may not be or remain in the money during the period they are exercisable and prior to their expiration and, therefore, it is possible that the Warrants may not be exercised prior to their maturity on March 15, 2028, even if they are in the money, and as such, may expire worthless with minimal proceeds received by us, if any, from the exercise of Warrants. To the extent that any of the Warrants are exercised on a “cashless basis,” we will not receive any proceeds upon such exercise. As a result of the above and coupled with the level of Redemption Rate, we do not expect to rely on the cash exercise of Warrants to fund our operations. Instead, we intend to rely on other sources of cash discussed elsewhere in this registration statement to continue to fund our operations. See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources.” If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or commercialization for one or more of our product candidates, and in turn will adversely affect our business prospects.

***We had net cash outflow from operating activities in the three fiscal years ended March 31, 2025 and may continue to experience such cash outflow for the foreseeable future***

We had net cash used in operating activities of RMB182.5 million, RMB295.2 million and RMB121.0 million ($16.9 million) for the fiscal years ended March 31, 2023, 2024 and 2025, respectively, and we may not be able to achieve or sustain positive operating cash inflows for the foreseeable future. Although we believe we have sufficient working capital to fund our operations, if in any case we are unable to maintain adequate liquidity for operating activities, we may not be able to fund our research and development and commercialization activities and to meet our capital expenditure requirements, which may have a material adverse effect on our business prospects, financial condition and results of operations.

***We incurred net liabilities in the past fiscal years. Despite our improved financial position, we may continue to have net liabilities in the foreseeable future and be exposed to liquidity risk.***

As of March 31, 2024 and March 31, 2025, we had equity balances of RMB585.2 million and RMB499.8 million ($69.6 million), respectively. However, the historical presence of net liabilities (total deficit) in prior years can expose us to the risk of shortfalls in liquidity. Such liquidity risk could necessitate seeking financing from external sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed can have a material adverse effect on our business and prospects.

Historically, we had to allocate significant financial resources to serve our large balance of indebtedness, rather than to fund our operating activities and investments in research and development. This allocation constraint may continue to limit our capital flexibility and, in turn, adversely affect the development timetable of our product candidates. Moreover, timely interest and principal repayments posed challenges, possibly triggering cross-defaults with other debt, as applicable, as well as limiting our ability to obtain further debt financing. While the net liabilities position has been improved with the conversion of the convertible redeemable preferred shares upon the consummation of the Business Combination, it’s essential to acknowledge that risks stemming from our historical financial structure remain. Given our historical reliance on external equity and debt financing, the recurrence of such issues could have a material adverse effect on our business, financial condition and results of operations. The possibility of incurring net liabilities in the future still exists, and should that happen, our liquidity and our ability to raise funds, obtain bank loans, meet debt obligations and pay dividends will be materially and adversely affected.

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***If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.***

As of March 31, 2023, 2024 and 2025, we had intangible assets of RMB78.1 million, RMB71.2 million and RMB72.9 million ($10.1 million), respectively, which primarily consisted of patents relating to our PIKA adjuvant technology, other licenses, certificates and intellectual properties relating to our business operations and land use rights relating to our lands in the PRC. Our determination on whether intangible assets are impaired requires an estimation on recoverable amount of the intangible assets, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed our recoverable amount, and our intangible assets may be impaired. As a result, we may be required to significantly write-off our intangible assets and record a significant impairment loss, which would have a material adverse effect on our business, results of operations and financial condition.

***We are subject to credit risks arising from some customers. If we experience delays in collecting or if we are unable to collect trade receivables from customers, our results of operations and financial condition could be adversely affected.***

We commenced the sale of YSJA™ rabies vaccine in October 2020. In line with market practice, we typically grant our customers a credit period of four months. As of March 31, 2023, 2024 and 2025, we had accounts receivable of RMB463.1 million, RMB444.2 million and RMB500.9 million ($69.8 million), respectively. As of March 31, 2025, our accounts receivable primarily represented amounts due from county-level CDCs attributable to the sales of YSJATM rabies vaccines. As a result, we may be exposed to credit risks. We recorded allowance for doubtful accounts for accounts receivable, net of RMB24.4 million, RMB29.4 million and RMB30.3 million ($4.2 million) as of March 31, 2023, 2024 and 2025, respectively. The increase in the year-end accounts receivable balance is primarily attributable to the financial constraints and limited liquidity experienced by local governments in certain regions, which has led to delays in the settlement of payments.

We cannot assure you that our customers could settle trade receivables in a timely manner, or at all, or that we can properly assess and respond in a timely manner to changes in their credit profile. If our customers’ cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be unwilling, to pay trade receivables owed to us promptly or at all. We may also be involved in litigations and disputes with our customers related to such credit risks. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with our customers in a manner that may adversely affect our business, results of operations and financial condition.

***We have incurred and may continue to incur substantial share-based payment expenses, which may have a material and adverse effect on our results of operations and financial condition.***

We have adopted the 2020 Share Incentive Plan and the 2024 Share Incentive Plan, and granted certain awards to our directors, employees and consultants pursuant to the terms of such plans. The 2024 Share Incentive Plan was amended in March 2025 (the “Amended 2024 Share Incentive Plan”). We believe the grant of share-based compensation is important to our ability to attract, retain and motivate our management team and qualified employees. The maximum number of ordinary shares that may be issued under the 2020 Share Incentive Plan is 8,750,000 ordinary shares. Pursuant to section 3.1 of the 2024 Share Incentive Plan, the maximum aggregate number of ordinary shares, par value US$0.00002 per share, which may be issued pursuant to all awards under the 2024 Share Incentive Plan (the “2024 Award Pool”) shall initially be 5,713,064 Shares, plus an annual increase on the first day of each fiscal year during the term of the 2024 Share Incentive Plan commencing with the fiscal year beginning on April 1, 2025, by (i) an amount equal to 1% of the total number of ordinary shares issued and outstanding on the last day of the immediately preceding fiscal year, or (ii) such lesser number of ordinary shares as may be determined by the board of directors (the “Evergreen Provision”). To reflect the share consolidation effective on October 1, 2024, and the early utilization of the ordinary shares reserved for issuance under the 2024 Share Incentive Plan pursuant to the Evergreen Provision, the 2024 Award Pool under the Amended 2024 Share Incentive Plan was adjusted to 2,479,385 ordinary shares, par value US$0.0002 per share. The remainder of the Amended 2024 Plan remains the same as the 2024 Share Incentive Plan. As of June 30, 2025, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2020 Share Incentive Plan and Amended 2024 Share Incentive Plan was 875,000 and 2,479,385, respectively. For details, see “Item 6. Directors, Senior Management and Employees—B. Compensation—Share Incentive Plans.”

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We recorded share-based compensation expenses of RMB3.5 million, RMB9.8 million and RMB13.6 million ($1.9 million) for the fiscal years ended March 31, 2023, 2024 and 2025, respectively. We expect to further incur share-based payment expenses in the future as a result of any further grant, which will also dilute existing shareholders’ shareholding.

**Risks Related to Our Intellectual Property**

***The issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain, and there can be no assurance that any of our technology, marketed product or product candidates will be protectable or remain protected by valid and enforceable patents. If we are unable to obtain and maintain patent protection for our marketed product and product candidates, or if the scope of such patent protection obtained is not sufficiently broad, third parties may compete directly against us.***

Our success depends, in part, on our ability to protect our marketed product and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect our marketed product and product candidates and technology that we consider commercially important by filing PRC and international patent applications. We do not currently own a valid composition of matter patent for our marketed product, YSJA™ rabies vaccine, and rely on our know-how, proprietary techniques and patents in relation to our manufacturing process, together with established safety and efficacy profile as well as reputation, to protect our marketed product. If we are unable to obtain or maintain patent or other statutory protection with respect to any of our marketed product and product candidates and the technology we develop, or if the scope of such patent or other statutory protection obtained is not sufficiently broad, third parties may compete directly against us, and our business, financial condition, results of operations, and prospects could be materially and adversely affected.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot assure you that our patent applications will result in the issuance of any patents that effectively protect our product candidates. The scope of a patent application can be significantly reduced before the patent is issued, and it can be reinterpreted after issuance. The scope of protection for issued patents may also vary across different jurisdictions. Changes in either the patent laws or interpretation of the patent laws in various jurisdictions may diminish the value of our patents or narrow the scope of our patent protection. Patent may not be issued 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. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of considerable litigation in recent years. Third parties may dispute that our product candidates are not validly protected by the underlying patents relating to PIKA adjuvant due to the uncertainties as to the interpretation of the scope and other parameters relating to such patents, and as such, they may attempt to manufacture and commercialize products similar to our product candidates without infringing upon any valid patents we hold in the relevant jurisdictions. We cannot assure you we will successfully defend the merits and scope of our patent protection and we may be forced to tolerate and compete with such similar products. Consequently, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain, and we cannot assure you that any of our technology, marketed product or product candidates will be protectable or remain protected by valid and enforceable patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in China, Singapore, the United States and other countries or jurisdictions. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned patent rights, allow third parties to commercialize our technology, marketed product or product candidates and compete directly with us without payment to us. Such proceedings also may result in substantial costs and require significant time from our scientists and management. our competitors or other third parties may be able to circumvent our owned patents by developing similar or alternative technologies or products in a non-infringing manner. Furthermore, the terms of patents are finite. See “—If We do not obtain patent term extension and data exclusivity for any of our product candidates we may develop, our business may be materially harmed.”

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As a result, our owned patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or 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 patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Many government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application and transfer process. We are also dependent on our agents to take the necessary action to comply with these requirements. We cannot assure that we or our agents will comply with these requirements in a timely manner. We did not experience any material failure to comply with these requirements in the three fiscal years ended March 31, 2025 that resulted in any material adverse effect on the scope or validity of our owned patents. If we fail to comply with these requirements, we may be subject to additional late payment fines or injunctions. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***If we do not obtain patent term extension and data exclusivity for any of our product candidates we may develop, our business may be materially harmed.***

The Patent Law of China, amended in October 2020 and effective June 1, 2021, provides that, upon the requests of the patentee, the patent administrative authorities shall grant a limited patent term extension to the patent relating to a new drug that was approved in China, as compensation for patent term lost during the NMPA regulatory review process of such new drug. The compensation period shall not exceed five years, and the total validity period of patent rights for such approved new drug shall not exceed 14 years after the market approval of such drug. During the regulatory review process of a new drug, should any disputes arise due to the patent relating to the new drug, for which approval is being sought, whether the patent will be infringed by the proposed drug may be answered by a people’s court upon the requests of the relevant parties before the final approval is provided. The NMPA may decide whether to suspend the approval review process of the proposed drug based on the judgment of the people’s court. On July 4, 2021, the NMPA and the China National Intellectual Property Administration issued Implementing Measures for the Early Settlement Mechanism for Drug Patent Disputes (for Trial Implementation). On the same day, the Supreme People’s Court of the PRC issued Provisions of Supreme People’s Court on Several Issues Concerning the Application of Law in the Hearing of Civil Cases Involving Disputes over Patent Rights Relating to Drugs under Application for Registration, which became effective on July 5, 2021. However, relevant regulations are implemented for a relatively short period of time and therefore the enforcement of laws and regulations regarding the patent linkage system remain uncertain in China. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

***Developments in patent law could have a negative impact on our business.***

Changes in either the patent laws or interpretation of the patent laws in China, the United States and other government authorities could increase the uncertainties and costs surrounding the prosecution of patent applications, and the enforcement or defense of issued patents. Such changes could potentially diminish the value of our patents or narrow the scope of our patent protection. Court rulings could also impact how patents are interpreted and enforced. For example, Leahy-Smith America Invents Act (the “America Invents Act”), which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a “first-to-invent” system to a “first investor-to-file” system as of March 2013, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These include allowing third party submission of prior art to the United States Patent and Trademark Office (the “USPTO”) during patent prosecution and additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings, including post grant review, inter parties review, and derivation proceedings. The PRC laws on the protection of intellectual property rights of drugs are also evolving. The Patent Law of the PRC and the Implementation Rules of the Patent Law of the PRC are applicable to drugs protected by patents. On October 17, 2020, the Standing Committee of the National People's Congress of the PRC passed the decision to amend the Patent Law of the PRC. The amended patent law came into effect on June 1, 2021. The amended Patent Law provides, among other things, that (1) in case an invention patent is only granted after four years or more from its filing date and three years or more after a request for substantive examination was filed, the patentee can request for an extension of patent term for any unreasonable delay; and (2) the patent term extension will also be available for pharmaceutical-related patents, similar to a supplementary protection certificate in other jurisdictions, to compensate the time spent in obtaining marketing authorization for a drug. The maximum extension for drug-related patents shall be five years with a total effective patent term not exceeding 14 years after the marketing authorization of such drug is obtained. The applications for such extensions and their approval are provided for in the Patent Examination Guidelines.

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Changes to patent law may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not entirely clear what, if any, impact the changes to patent law will have on the cost of prosecuting our patent applications and our ability to obtain patents based on our discoveries and to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed.***

In addition to the protection afforded by issued patents and pending patent applications, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We also seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties that have access to them, such as our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence of confidentiality agreements and other contractual restrictions. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. If a third party illegally disclosed or misappropriated our trade secrets, it could be difficult, expensive and time-consuming to enforce a claim, including through intellectual property litigations or other proceedings, and the outcome is unpredictable. In addition, courts in China and other jurisdictions inside and outside the United States may be less prepared, less willing or unwilling to protect trade secrets. Our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties.

For example, competitors could purchase our marketed product and product candidates, attempt to replicate some or all of the competitive advantages we derive from our development efforts, and design around our intellectual property protecting such technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be disclosed or independently developed by a competitor, we would have no right to prevent them, or others to whom they communicate it, from using that technology or information to compete against us, which may have a material adverse effect on our business, prospects, financial condition and results of operations.

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our other intellectual property, we may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as inventors or co-inventors. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail to defend 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 intellectual property. 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.

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***We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of competitors or their current or former employers or are in breach of non-competition or non-solicitation agreements with competitors or other third parties.***

We could in the future be subject to claims that we or our employees, consultants or advisors have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of current or former employers, competitors or other third parties. Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not improperly use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have breached the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer, competitor or other third parties.

Litigation may be necessary to defend against the above-described claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or competitors. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or threat of such litigation may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product and product candidates, which would have a material adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. 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. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not be able to protect and effectively enforce our intellectual property rights including patents.***

We may not be able to identify the infringement of our intellectual property rights including patents at an early stage and may forfeit the best opportunity to enforce the protection of such intellectual property rights. Even if we are able to enforce intellectual property rights in a timely manner, the legal system in certain jurisdictions including China may have generally provided less protection for intellectual property rights than certain other legal systems, such as in the United States. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to them or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of courts in different and other jurisdictions in handling intellectual property litigation varies, and outcomes are unpredictable. This variation and unpredictability could make it more difficult for us to prevent competitors from using our patented technology in certain countries. Furthermore, such litigation may be time-consuming, require significant expenditures of cash, resources and management efforts and could harm our business, financial condition and results of operations. As a result, we may not be able to enforce our intellectual property right and effectively stop infringe, and an adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation. Furthermore, technological advances could potentially make our patents obsolete, reducing their protective value and possibly rendering our products less competitive.

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

We own or have filed application for patents for our product candidates in over 14 countries and regions. Filing, prosecuting, maintaining and defending patents on our product candidates in all countries and regions throughout the world could be prohibitively expensive for us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and may also export otherwise infringing products to jurisdictions where we have patent protection, but where enforcement rights are not strong. These products may compete with our marketed product and product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

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 or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Furthermore, 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 patent. If we 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.

***We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful. our patent rights relating to our product candidates could be found invalid or unenforceable if challenged in court or before other authorities.***

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 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, time consuming and vary significantly across different jurisdictions. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. We cannot assure you we will be able to prevent third parties from infringing upon or misappropriating our intellectual property in the future. Litigation could result in substantial costs and diversion of management resources, which could harm our business operations and financial results.

In addition, in an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our owned patents do not cover such third-party technology. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our 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. Moreover, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

Furthermore, third parties may initiate legal proceedings before administrative bodies in China and/or other jurisdictions, even outside the context of litigation, against us with respect to our owned intellectual property to assert challenges to such intellectual property rights. Such mechanisms include re-examination, inter parties review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. We are not involved in any pending proceeding where a third party attempted to challenge the validity, enforceability or scope of our intellectual property rights as of the date of this Annual Report. We cannot assure you that we will always prevail in any such proceeding as our outcome is generally unpredictable. Our cost of any patent litigation or similar proceeding could be substantial, and we may consume significant management and other personnel time. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation.

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An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one or more of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidates. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor’s patents, we could be prevented from marketing our products in one or more foreign countries. 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.

Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations and prospects.

***Intellectual property litigation and proceedings could cause us to spend substantial resources and distract our personnel from our normal responsibilities.***

Third parties who bring successful claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our marketed product and product candidates. Defense of these claims, regardless of their merits, 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 or misappropriation 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 marketed product and product 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 marketed product and product candidates. We cannot predict whether any required license would be available at all or whether we would be available on commercially reasonable terms, and we may fail to obtain any of these licenses on commercially reasonable terms, if at all. In the event we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our marketed product and product 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 our other third parties’ intellectual property claims may cause us to incur significant expenses and could distract our personnel from our 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, we could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales and marketing activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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 and more mature and developed intellectual property portfolios.

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.

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***The success of our business may depend on licensing, collaboration and other strategic arrangements with third parties, and we cannot assure you that our licensing, collaboration or other strategic efforts will succeed or that we will derive any benefits from these arrangements.***

We have entered into collaboration agreements with third parties from time to time to jointly develop vaccines and other biologics. See “Item 4. Information on the Company—B. Business Overview—Our Strategic Collaborations” for details. The success of our business strategy depends, in part, on our ability to enter into licensing, collaboration and other strategic arrangements and to manage effectively the resulting relationships. We cannot assure you that the organizations or institutes we collaborate with will not terminate such cooperation’s or enter into collaborative relationships with our competitors in the future.

Our ability to enter into agreements with commercial partners depends in part on our ability to convince them of the value of our technology, expertise, know-how or distribution channel. This may require substantial time and effort on our part. While we anticipate expending substantial funds and management efforts, we cannot assure you that collaborative relationships will result or that we will be able to negotiate additional collaborative agreements in the future on acceptable terms, if at all. Furthermore, we may incur significant financial commitments to partners in connection with potential licenses, collaboration or other agreements. In addition, we may not be able to control the areas of responsibility undertaken by our commercial partners and our business may suffer greatly should these partners prove unable to carry a product candidate forward to full commercialization, lose interest in dedicating the necessary resources toward developing any such product quickly, fail to implement the appropriate quality control measures in their manufacture of the products licensed to them by us or decline to expend the necessary effort or resources to market and sell such products.

Moreover, third parties may terminate our licensing, collaboration and other strategic arrangements if we do not perform as required under these arrangements. In addition, these third parties may also breach or terminate their agreements with us or otherwise fail to conduct their activities in connection with our relationships in a timely manner. If we or our partners terminate or breach any of our licenses or relationships, we may:

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|  | ● | lose the rights to manufacture, market or sell certain products; |

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|  | ● | experience significant delays in the development or commercialization of product candidates; |

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|  | ● | not be able to obtain any other licenses on acceptable terms, if at all; |

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|  | ● | need to allocate resources for damage control and remediation which would otherwise have been used for commercialization and business activities; |

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|  | ● | initiate legal proceedings against our former partners or have such proceedings initiated against us and |

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|  | ● | incur liability for damages. |

Licensing arrangements and collaborative relationships in our industry can be very complex, particularly with respect to intellectual property rights. Disputes may arise in the future regarding ownership rights to technology developed by or with other parties. These and other possible disagreements between us and third parties with respect to our licenses or their collaborative relationships could lead to delays in the research, development, manufacture and commercialization of current product or product candidates. These disputes could also result in litigation or arbitration, both of which are time-consuming and expensive. These third parties also may pursue alternative technologies or product candidates either on their own or in collaborative relationships with others in direct competition with us.

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***Intellectual property rights do not necessarily address all potential threats.***

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:

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|  | ● | others may be able to make vaccines and other biologics that are similar to any marketed product or product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we may own or in-license in the future; |

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|  | ● | we, patent owners of patent rights that we may in-license, or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future; |

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|  | ● | we, patent owners of patent rights that we may in-license, or current or future collaborators might not have been the first to file patent applications covering certain of our or their inventions; |

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|  | ● | others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights; |

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|  | ● | it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents; |

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|  | ● | issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors; |

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|  | ● | 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; |

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|  | ● | we may not develop additional proprietary technologies that are patentable; |

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|  | ● | the patents of others may harm our business; and |

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|  | ● | we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may discover certain technologies containing such trade secrets or know how through independent research and development and/or subsequently file a patent covering such intellectual property. |

Should any of these events occur, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Our General Operations**

***While the lockdown in China ended, the aftereffect of the pandemic may continue to disrupt global economies and markets. We could be adversely affected by the ongoing global impacts and uncertainties of the COVID-19 pandemic or similar pandemics in the future.***

Beginning in early 2020, there was an outbreak of a novel strain of coronavirus, COVID-19. Governments across the world took a number of actions, including imposing restrictive policies which were designed to limit intercity or cross-border travels, request residents to remain at home and avoid public gatherings, and encourage work-from-home arrangements, among other actions.

Many of the restrictive measures previously adopted by the PRC governments at various levels to control the spread of the COVID-19 virus were revoked or replaced with more flexible measures since December 2022. While the revocation or replacement of the restrictive measures to contain the COVID-19 pandemic could have a positive impact on our normal operations, it may also shift the public’s interest in COVID-19 vaccines. Moreover, there has recently been and may continue to be an increase in COVID-19 cases in China, and as a result, we experienced temporary disruption to our operations, including constraints and disruptions in the supplier chain, a significant number of employees being infected with COVID-19, and a decrease in output. The extent to which the COVID-19 pandemic impacts our business, prospects and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the pace of global economic recovery, shifts in supply chains, changes in market behavior, and adaptations to new norms in the post-pandemic world. The lingering impact of COVID-19 pandemic could limit the ability of customers, suppliers, vendors and business partners to perform their obligations. Even though the COVID-19 pandemic has subsided, difficult macroeconomic conditions, such as decreases in per capita income and level of disposable income, increased and prolonged unemployment or a decline in consumer confidence as a result of the COVID-19 pandemic, as well as reduced spending by businesses, could each have a material adverse effect on the demand for our products. We cannot accurately forecast the potential impact of additional outbreaks, further shelter-in-place or other government restrictions implemented in response to such outbreaks, or the impact on the ability of our suppliers and other business partners to remain in business as a result of the lingering impact of the pandemic or any additional outbreaks.

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***We have limited operating experience and management teams in the international market. Our international expansion plan may expose us to risks associated with international manufacturing, sales and operations.***

We established research and development bases in China, Singapore and the Philippines, and may further expand our manufacturing, customer bases and operations globally. However, we have limited operating experience and management teams in the international market. As of the date of this Annual Report, we have not started in setting up our international operation for the sales, marketing and distribution of our immunological biologics. Managing an international organization is difficult, time-consuming and expensive. Our lack of a track record in operating a business internationally increases the risk that any current or potential future international expansion efforts may not be successful. In addition, conducting international operations subjects us to new risks that we have not generally faced. These risks that may materially adversely affect our ability to attain or sustain profitable operations include:

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|  | ● | localization of our products, including adaptation to local practices and regulatory requirements; |

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|  | ● | production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; |

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|  | ● | efforts to enter into collaboration with third parties in connection with our international sales and operations that may increase our expenses or divert our management’s attention from the acquisition or development of product candidates; |

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|  | ● | changes in the political and cultural climate or economic condition of a specific country or region; |

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|  | ● | lack of familiarity with and unexpected changes in applicable foreign regulatory regimes; |

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|  | ● | difficulty of effective enforcement of contractual provisions in local jurisdictions; |

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|  | ● | more extended accounts receivable payment cycles and difficulties in collecting payments; |

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|  | ● | difficulties in managing and staffing overseas operations; |

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|  | ● | compliance with tax, employment, immigration and labor laws for employees traveling abroad; |

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|  | ● | workforce uncertainty and labor unrest; |

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|  | ● | fluctuations in foreign currency exchange rates, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country or region; |

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|  | ● | potentially adverse tax consequences, including the complexities of transfer pricing, foreign value-added tax systems and restrictions on the repatriation of earnings; |

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|  | ● | unexpected changes in tariffs, trade barriers and regulatory requirements; |

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|  | ● | dependence on certain third parties, such as local distributors or joint venture partners, with whom we do not have extensive experience; |

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|  | ● | potential third-party patent rights infringement and difficulties to enforce intellectual property rights; |

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|  | ● | increased financial accounting and reporting burdens and complexities; |

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|  | ● | political, social, and economic instability abroad, including war and terrorism, and security concerns in general such as natural disasters; and |

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|  | ● | reduced or varied protection for intellectual property rights in certain jurisdictions. |

Operating in international markets also requires significant management attention and financial resources. We cannot assure you that the investment and additional resources required to establish operations and manage growth in other countries would produce anticipated levels of revenue or profitability, and that any international expansion would be successful and would not have a material adverse effect on our business, financial condition and results of operations.

***We face certain risks related to our real properties.***

We lease multiple real properties in several countries from third parties. Should disputes arise due to our use of or title encumbrances on such property or government action, we may encounter difficulties in continuing to lease such property and may be required to relocate. As of the date of this Annual Report, we are not aware of any claim or challenge brought by any third party or governmental authority concerning the use of such leased property. We cannot assure you that in the future, we may not encounter such challenges. In addition, in the event of relocation, we may incur additional costs and face logistical complexities, reestablishment of business relationships, and operational disruption, which could adversely affect our daily operation and cause an impact on our financial condition.

In addition, as a vaccine manufacturing enterprise, we currently hold certain parcel of lands to expand our manufacturing or R&D capacities. Under current PRC laws and regulations, if we fail to commence the construction for more than one year from the commencement date stipulated in the land use right grant contracts, the relevant PRC land bureau may serve an investigation notice and impose an idle land fee of up to 20% of the land use right premium on us unless the delay is caused by government actions or force majeure. If we fail to commence the construction for more than two years, the land may be subject to forfeiture by the PRC government unless the delay is caused by government actions or force majeure. In addition to the administrative penalties, we may be subject to civil liability as stipulated under the contracts. We cannot assure you that we are and will be fully in compliance with the obligations under the land use right grant contract or listing-for-sale letters in the future due to factors which are beyond our control. If we fail to comply with the terms of any land grant contract or listing-for-sale confirmation letter as a result of delays in any reasons other than government actions or force majeure, we may have financial loss or lose our previous investments in the land, which may have a material adverse effect on our business, results of operations and financial condition.

Moreover, we are required to obtain a series of approvals, filings, permits or licenses before we commence the construction under PRC laws and regulations. We cannot assure you that we have obtained and fully complied with, or will be able to obtain and fully comply with such approvals, filings, permits, licenses or other requisite procedures. If we are found to be non-compliant with, relevant laws and regulations, the relevant authorities may suspend or halt our construction or production as well as impose fines and penalties. For example, in case we failed to obtain the relevant approval from environmental authorities, if necessary, for our construction projects before our construction activities, a fine up to 5% of the total investment amount of such construction project might be imposed on us. Any non-compliance of relevant requirements on, including but not limited to construction, environmental protection, fire prevention and safety conditions, may adversely affect our results of operations and financial condition.

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***We may be subject to fines and penalties under applicable PRC laws and regulations for failure to make adequate contributions to social insurance and housing reserve fund for our employees.***

Pursuant to relevant PRC laws and regulations, employers are obligated to directly and duly make contributions in respect of social insurances and housing reserve fund for their employees. We cannot assure you that our employment practice has been and will at all times be deemed to be in full compliance with labor-related laws and regulations in China, which may subject us to labor disputes or government investigations and administrative penalties. If we are deemed to have violated relevant labor laws and regulations, we could be required to provide additional compensation to our employees or pay penalties, and our reputation, business, financial condition and results of operations could be materially and adversely affected. Historically, we did not make adequate social insurance and housing provident fund contributions for our employees as required by the relevant PRC laws and regulations.

We rectified the issue and made adequate social insurances and housing reserve fund contributions for all of our eligible employees. We paid all the overdue principal and late charges in relation to our social insurances and housing reserve fund contributions for all current employees and certain former employees, and we are communicating with the remaining former employees to complete the administrative procedure as the prerequisite for making such payments as of the date of this Annual Report. We also made provision for the historical inadequate contributions in our financial statements. As of the date of this Annual Report, we are not aware of any pending orders or demands from the relevant PRC government authorities requesting we pay these unpaid contributions, complete the registration or pay any penalties. If the relevant PRC government authorities order us to make the outstanding contributions or impose penalties on it, or if our provision in our financial statements turns out to be insufficient, our business, financial condition and results of operations could be adversely affected. As the interpretation and implementation of labor-related laws and regulations are still evolving, we cannot assure you that our current employment practices do not and will not violate labor-related laws and regulations in China, which may subject it to labor disputes or government investigations. In addition, we may incur additional expenses in order to comply with such laws and regulations, which may adversely affect our business and profitability.

***Enhanced scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on potential acquisitions we may pursue in the future.***

Pursuant to the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises (“SAT Circular 698”), issued by the PRC’s State Taxation Administration, or the SAT, on December 10, 2009, where a foreign investor transfers the equity interests of a resident enterprise indirectly via disposition of the equity interests of an overseas holding company, or an “indirect transfer,” and such overseas holding company is located in a tax jurisdiction that (1) has an effective tax rate less than 12.5% or (2) does not tax foreign income of its residents, the foreign investor shall report the indirect transfer to the competent PRC tax authority. The PRC tax authority will examine the true nature of the indirect transfer, and if the tax authority considers that the foreign investor has adopted an “abusive arrangement” in order to avoid PRC tax, we may disregard the existence of the overseas holding company and re-characterize the indirect transfer and as a result, gains derived by the non-PRC tax resident enterprises from such indirect transfer may be subject to PRC withholding tax at a rate of up to 10%.

On February 3, 2015, the SAT issued the Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises (“SAT Bulletin 7”) to supersede existing provisions in relation to the “indirect transfer” as set forth in SAT Circular 698, while the other provisions of SAT Circular 698 remained in force. Pursuant to SAT Bulletin 7, where a non-resident enterprise indirectly transfers properties such as equity in PRC resident enterprises without any justifiable business purposes and aiming to avoid the payment of enterprise income tax, such indirect transfer must be reclassified as a direct transfer of equity in PRC resident enterprise. To assess whether an indirect transfer of PRC taxable properties has reasonable commercial purposes, all arrangements related to the indirect transfer must be considered comprehensively and factors set forth in SAT Bulletin 7 must be comprehensively analyzed in light of the actual circumstances.

On October 17, 2017, the SAT issued the Announcement of the State Administration of Taxation on Matters Concerning Withholding of Income Tax of Non-resident Enterprises as Source (“SAT Bulletin 37”), which repealed the entire SAT Circular 698 and the provision in relation to the time limit for the withholding agent to declare to the competent tax authority for payment of such tax of SAT Bulletin 7. Pursuant to SAT Bulletin 37, the income from a property transfer, as stipulated in the second item under Article 19 of the Enterprise Income Tax Law, shall include the income derived from transferring such equity investment assets as stock equity. The balance of deducting the equity’s net value from the total income from equity transfer shall be taxable income from equity transfer. Where a withholding agent enters into a business contract, involving the income specified in the third paragraph of Article 3 in the Enterprise Income Tax Law, with a non-resident enterprise, the tax-excluding income of the non-resident enterprise will be treated as the tax-including income, based on which the tax payment will be calculated and remitted, if it is agreed in the contract that the withholding agent shall assume the tax payable.

During the effective period of SAT Circular 698 and by the application of SAT Bulletin 7 and SAT Bulletin 37, some intermediary holding companies were actually looked through by the PRC tax authorities, and consequently the non-PRC resident investors were deemed to have transferred the PRC subsidiary and PRC corporate taxes were assessed accordingly. It is possible that we or our non-PRC resident investors may at some point be at risk of being taxed under SAT Bulletin 7 and SAT Bulletin 37 and may be required to expend valuable resources to comply with SAT Bulletin 7 and SAT Bulletin 37 or to establish that we or our non-PRC resident investors should not be taxed under SAT Bulletin 7 and SAT Bulletin 37, which may have an adverse effect on our financial condition and results of operations or such non-PRC resident investors’ investment in us.

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***We depend substantially on the continuing efforts of our senior executives, key research and development personnel and commercialization personnel, and our business and prospects may be severely disrupted if we lose their services.***

Our future success depends heavily upon the continued service of our senior management and key research and development and commercialization personnel. In particular, we rely on the healthcare industry-related experience and professional knowledge of our senior officers. Our R&D team is critical to the development and commercialization of product candidates and realization of the potential benefits of our intellectual property, including our proprietary PIKA immunomodulatory technology platform. Our ability to attract and retain key personnel, in particular, senior management, key research and development personnel and commercialization personnel, is a critical aspect of our competitiveness. Competition for these individuals could require us to offer higher compensation and other benefits in order to attract and retain them, which would increase our operating expenses and, in turn, could materially and adversely affect our results of operations and financial condition. We may be unable to attract or retain the personnel required to achieve our business objectives, and failure to do so could severely disrupt our business and prospects. The loss of any of our key employees, including senior executives, key research and development personnel or commercialization personnel, could materially harm our business and prospects.

We do not maintain key-person insurance for members of our management team. If we lose the services of any senior management member, we may not be able to locate suitable or qualified replacements and may incur additional expenses to recruit and train new personnel, which could severely disrupt our business and prospects. Furthermore, if any of our executive officers joins a competitor or forms a competing company, we may lose a significant number of our existing customers, which could have a material adverse effect on our business and revenues. Although each of our executive officers has an agreement with us that contains confidentiality and non-competition undertakings regarding their employment, disputes may arise between our executive officers and us, and these agreements may not be enforced in accordance with their terms.

***We may pursue collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other strategic investment or arrangements, which may fail to produce anticipated benefits and adversely affect our business.***

We collaborate with research organizations and government agencies to supplement our in-house efforts and advance the development of our product candidates. We may pursue other opportunities for collaboration, in-licensing, joint ventures, acquisitions of products, assets or technology, strategic alliances, or partnerships that we believe would be complementary to or promote our existing business. However, initiating, negotiating, and finalizing these potential transactions can be a long-drawn, complex process filled with uncertainties. Other companies, including those with substantially greater financial capacity, marketing networks, technological capabilities, business expertise, or other business or governmental resources, may compete with us for these opportunities or arrangements. Consequently, these organizations may be in a stronger position to pursue and secure the same opportunities we are interested in, putting us at a competitive disadvantage. Moreover, identifying suitable opportunities or arrangements that align with our strategic objectives can be challenging and may require a significant amount of time and resources. Even after identifying a potential opportunity, we may not be able to identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all.

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We have limited experience with respect to these business development activities. Management and integration of a licensing arrangement, collaboration, joint venture or other strategic arrangement may disrupt our current operations, decrease our profitability, result in significant expenses, or divert management resources that otherwise would be available for our existing business. We may not realize the anticipated benefits of any such transaction or arrangement.

Furthermore, partners, collaborators or other parties to such transactions or arrangements may fail to fully, or at all, perform their obligations or meet our expectations or cooperate with us satisfactorily for various reasons, including risks or uncertainties related to their business and operations. There may be conflicts or other collaboration failures and inefficiencies between us and the other parties.

Such transactions or arrangements may also require actions, consents, approvals, waivers, participation or involvement of various degrees from third parties, such as regulators, government authorities, creditors, licensors or licensees, related individuals, suppliers, distributors, shareholders or other stakeholders or interested parties. There is no assurance that such third parties will be cooperative as we desire, or at all, in which case we may be unable to carry out the relevant transactions or arrangements.

Any transaction we undertake would need to be integrated with our current operations. Integration issues, including business limitations, culture clashes, unanticipated costs, undisclosed liabilities, and loss of key employees, can impede our operational efficiency and productivity, thereby adversely affecting our business, results of operations and financial condition.

***We may not be able to complete new acquisitions successfully. Even if we successfully acquire companies, products or technologies, we may face integration risks and costs associated with those acquisitions that could negatively impact our business, financial condition and results from operations.***

Acquisitions have been, and are expected to continue to be, an important part of our growth strategies. For example, we have established our proprietary PIKA immunomodulatory technology platform through the acquisition of NewBiomed (now Singapore LakeShore) in June 2010. If we are presented with appropriate opportunities, we may make additional acquisitions of complementary businesses, products, product candidates or technologies. Any such acquisitions will be dependent upon the continued availability of suitable acquisition targets at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify such acquisition targets. Moreover, other companies, many of which may have substantially greater financial, marketing, governmental and sales resources, are competing with us for the right to acquire such businesses, products, product candidates, qualifications or technologies. If an acquisition target is identified, the management and shareholders of the acquisition target may not select us as a potential partner or we may not be able to enter into agreements on commercially reasonable terms or at all. Furthermore, the negotiation and completion of potential acquisitions could cause significant diversion of our management’s time and resources and potential disruption of our ongoing business.

In addition, we cannot assure you we will realize the anticipated benefit of any acquisition or investment. If we acquire companies or technologies, we will face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations of an acquired company, integration of acquired technology with our products, diversion of our management’s attention from other business concerns, the potential loss of key employees or customers of the acquired business, the potential involvement in any litigation related to the acquired company, and impairment charges if acquisitions are not as successful as we originally anticipate. In addition, our results of operations may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets. As of March 31, 2023, 2024 and 2025, we had RMB78.1 million, RMB71.2 million and RMB72.9 million ($10.1 million) in intangible assets, net, respectively. Any failure to successfully integrate other companies, products, qualifications or technologies that we may acquire may have a material adverse effect on our business, financial condition and results of operations.

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***We will likely need substantial additional funding for our new and existing product development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.***

Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was RMB182.5 million, RMB295.2 million and RMB121.0 million ($16.9 million) the fiscal year ended March 31, 2023, 2024 and 2025, respectively. We expect our expenses to increase in connection with our ongoing activities, particularly as we expand the sale of YSJA™ rabies vaccine, advance the clinical trial of our product candidates and continue R&D of our preclinical stage product candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing and sales. In particular, the costs that may be required for the manufacture of any product candidate that receives regulatory approval may be substantial as we may have to: modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers or suppliers, increase labor capacity and insurance coverage, acquire and maintain new equipment and upgrade our budget on other manufacture-associated procedures such as waste management and product storage. We may also incur expenses as we create additional infrastructure to support our operations as a public company. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources.

Our ability to obtain additional capital in the future is subject to a variety of uncertainties, including:

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|  | ● | our future financial condition, results of operations, outcomes of ongoing research and development, and cash flows; |

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|  | ● | the condition of the U.S. and other capital markets in which we may seek to raise funds; |

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| --- | --- | --- |
|  | ● | investors’ perception of, and demand for, securities of biopharmaceutical companies; |

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| --- | --- | --- |
|  | ● | economic, political and other conditions or crises in China and elsewhere; |

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| --- | --- | --- |
|  | ● | regulatory changes; |

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|  | ● | availability of government grants and incentives; and |

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| --- | --- | --- |
|  | ● | considerations of tax, interest rates, competition, potential or ongoing litigations. |

If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts. To the extent 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. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

***Any catastrophe, including outbreaks of health pandemics and other extraordinary events, could have a negative impact on our business operations.***

We are vulnerable to natural disasters and other calamities. Fire, floods, typhoons, earthquakes, power loss, telecommunications failures, break-ins war, riots, terrorist attacks or similar events may give rise to server interruptions, breakdowns, system failures or Internet failures, which could cause the loss or corruption of data or malfunctions of software or hardware as well as adversely affect our ability to provide our services. Our vulnerability to such natural disasters and other calamities also extends to our physical facilities, equipment and other properties, resulting significant disruptions to our operations, delay or halt the production of our products, hinder the progress of our research and development, and cause loss of critical data. Moreover, such events could also affect our supply chain, leading to shortages of necessary materials or components. Inadequate insurance coverage or lack of resources to repair or replace the damaged facilities, equipment or other properties could exacerbate these challenges, significantly impacting our business financial condition and results of operations.

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Our business could also be adversely affected by the effects of Ebola virus diseases, H1N1 flu, H7N9 flu, avian flu, Severe Acute Respiratory Syndrome (SARS), COVID-19, or other existing or emerging epidemics in China and globally. Our operations could be disrupted if any of our employees is suspected of having any of the aforementioned epidemics or another contagious disease or condition, since we could require our employees to be quarantined and/or our offices to be disinfected. In addition, our business, results of operations and financial condition could be adversely affected to the extent that any of these epidemics harms the Chinese economy in general. For example, the outbreak, rapid spread, as well as its exacerbation, continuance or reoccurrence of COVID-19 throughout China and many other parts of the world since 2019 have already caused and may continue to cause an adverse and prolonged impact on the economy and social conditions in China and other affected countries. The existing clinical trials and the commencement of new clinical trials could be substantially disrupted, delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators’ trials as a result. The quality of our clinical trials can also be substantially and negatively affected or be subject to uncertainties due to the ongoing impact of COVID-19. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our product candidates, and could cause us to incur additional costs. If our employees or employees of our business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect the operating facilities. If we are not able to effectively develop and commercialize our product candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our product candidates or licensing our technologies as planned. All of the foregoing could have a material adverse effect on our results of operations and financial condition in the near term.

***A severe or prolonged downturn in Chinese or global economy could materially and adversely affect our business, results of operations, financial condition and prospects.***

While the global situation concerning COVID-19 has improved considerably due to widespread vaccination efforts and implementation of public health measures, there could still be potential repercussions from new variants of the virus, as well as uncertainties about the effectiveness and duration of existing marketed vaccines, which could influence future economic stability. Overall, its long-term effects on the global economy and specific sectors remain unclear. Even before the outbreak of COVID-19, the global macroeconomic environment was facing numerous challenges. The growth rate of the Chinese economy has been slowing since 2010, and the impact of COVID-19 on the Chinese economy in 2020 is likely to be severe. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies which had been adopted by the central banks and financial authorities of some of the world’s leading economies, including the United States and China, even before 2020. Unrest, terrorist threats and the potential for war in the Middle East, Ukraine, Russia and elsewhere may increase market volatility across the globe. There have also been concerns about the relationship between China and other countries, including the surrounding Asian countries, which may potentially have economic effects. In particular, there is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policies and the expected or perceived overall economic growth rate in China. Any severe or prolonged slowdown in the global or Chinese economy may materially and adversely affect our business, results of operations and financial condition.

***We may seek orphan drug exclusivity for some of our product candidates, which may not be successful.***

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the U.S. 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. Generally, if a drug with an orphan-drug designation (“ODD”) 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 U.S. FDA, from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period varies in different jurisdictions, which is seven years in the United States. Orphan drug exclusivity may be lost if the U.S. FDA 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.

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We obtained ODD for certain of our product candidates, including PIKA rabies vaccine and PIKA YS-ON-001. However, such designation cannot completely protect this product from future competition. The exclusivity may not effectively protect our product candidates 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 U.S. FDA can subsequently approve a different drug for the same condition if the U.S. 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.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

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

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

**Risks Related to Doing Business in China**

***Recent regulatory development in China may exert more oversight and control over listing and offerings that are conducted overseas. The approval, filing, and/or other requirements of PRC governmental authorities may be required under PRC laws, regulations or policies.***

We conduct a substantial portion of our business in China, including, manufacturing and sales of YSJATM rabies vaccines and certain R&D activities. As such, we and our subsidiaries are subject to PRC laws relating to, among others, restrictions over overseas listing, foreign investments and data security.

Under the current Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors adopted by six PRC regulatory agencies, including the Ministry of Commerce of the PRC (“MOFCOM”), the State-Owned Assets Supervision and Administration Commission, the SAT, the State Administration for Industry and Commerce, (currently known as the SAMR), the CSRC, and the SAFE in 2006 and amended in 2009 (the “M&A Rules”) include provisions that purport to require that an offshore special purpose vehicle that is controlled by PRC domestic companies or individuals and that has been formed for the purpose of an overseas listing of securities through acquisitions of PRC domestic companies or assets to obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle’s securities on an overseas stock exchange. On September 21, 2006, the CSRC published its approval procedures for overseas listings by special purpose vehicles. However, substantial uncertainty remains regarding the scope and applicability of the M&A Rules to offshore special purpose vehicles.

The Chinese government has recently sought to exert more control and impose more restrictions on China-based companies raising capital offshore and such efforts may continue or intensify in the future. On August 1, 2021, the CSRC stated in a statement that it had taken note of the new disclosure requirements announced by the SEC regarding the listings of Chinese companies and the recent regulatory development in China, and that both countries should strengthen communications on regulating China-related issuers.

On February 17, 2023, the CSRC issued the Trial Administrative Measures for Overseas Listing and five supporting guidelines, which came into effect on March 31, 2023. According to the Trial Administrative Measures for Overseas Listing, a filing-based regulatory regime is adopted to regulate both direct and indirect overseas securities offering and listing by the domestic companies. The Trial Administrative Measures for Overseas Listing provide the criteria of indirect overseas offering and listing by domestic companies that are subject to regulation. If the issuer meets both the following criteria, it will be deemed as indirect overseas offering and listing by domestic companies: (1) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (2) the main parts of the issuer’s business activities are conducted in mainland China, or its principal place(s) of business are located in China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or domiciled in China. The determination as to whether or not an overseas offering and listing by domestic companies is indirect, shall be made on a substance-over-form basis. The Trial Administrative Measures for Overseas Listing require that subsequent securities offerings of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three working days after the offering is completed and issuer that conducts its offering and subsequent securities offering and listing in other overseas markets shall be filed as an initial public offering, under which filing application with the CSRC shall be submitted within three working days after the application documents for offering and listing being submitted overseas. Further, a domestic company that seeks to directly or indirectly list its domestic assets in overseas markets through single or multiple acquisitions, share swaps, transfers of shares or other means, shall fulfil the filing procedure as an initial public offering. Where overseas application documents are not required, the filing shall be made within three working days after the first public disclosure of the specifics of the transaction is made by the listed company. In addition, pursuant to the CSRC press release regarding the Trial Administrative Measures for Overseas Listing published on its official website on February 17, 2023, a company having listed overseas before the effectiveness of the Trial Administrative Measures for Overseas Listing would only be subject to the filing requirements when conducting a follow-on offering of securities.

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Given that we had completed the Business Combinations and the listing of our ordinary shares on Nasdaq before the Trial Administrative Measures for Overseas Listing, went into effect we are not required to undergo the filing procedures with the CSRC in connection with these transactions. For our future capital - raising activities, if we fail to receive or maintain any requisite approval or filing from the CSRC, or the waiver for such approval or filing, in a timely manner, or at all, or inadvertently conclude that such approval or filing is not required, or if applicable laws, regulations or interpretations change and obligate us to obtain such approval or filing in the future, or we conceal any material fact or falsifies any major content in the filing documents we may be subject to rectifications, warnings, fines and penalties, limitations on our business activities in China, delay or restrictions on the contribution of the proceeds from further offerings into the PRC, or other sanctions that could have a material adverse effect on our business, financial condition, results of operations, reputation and prospects. The CSRC may also take actions requiring us or making it advisable for us to terminate future offerings. Such uncertainties and/or negative publicity regarding such requirements could cause our securities to decline significantly in value or become worthless.

Moreover, on September 24, 2024, the State Council released the Regulations for the Administration of Network Data Security (the “Network Data Regulation”). Under the Network Data Regulation, (1) a network data processor processing the personal information of 10 million or more individuals shall comply with the provisions governing network data processors processing important data (“processors of important data”); (2) where a network data processor outside the territory of the PRC processes the personal information of any individual within China and establishes a specialized agency or designates a representative within China in accordance with Article 53 of the Personal Information Protection Law of the PRC, it shall submit such information as the title of the relevant agency, the name of the representative, the contact information, and other information to the local cyberspace administration at the municipal level; and (3) when a network data processor discovers any risk, it shall immediately take remedial measures, inform users in a timely manner, and report the same to the appropriate department in accordance with the applicable provisions. If any damage is caused to national security or public interest, the network data processor shall also report the same to the appropriate department within designated hours. The Network Data Regulation came into effect on January 1, 2025. On December 28, 2021, the PRC government promulgated the 2022 Cybersecurity Review Measures, which came into effect on February 15, 2022. According to the 2022 Cybersecurity Review Measures, (i) critical information infrastructure operators that purchase network products and services and internet platform operators that conduct data processing activities shall be subject to cybersecurity review in accordance with the 2022 Cybersecurity Review Measures if such activities affect or may affect national security; and (ii) internet platform operators holding personal information of more than one million users and seeking to have their securities list on a stock exchange in a foreign country shall file for cybersecurity review with the Cybersecurity Review Office. As of the date of this Annual Report, neither we nor any of our subsidiaries has been required by any PRC governmental authority to apply for cybersecurity review, nor received any inquiry, notice, warning, sanction in such respect or been denied permission from any PRC regulatory authority to list on U.S. exchanges. Based on the opinion of our PRC counsel, Jingtian & Gongcheng, according to its interpretation of the currently in-effect PRC laws and regulations, we believe we are not subject to the cybersecurity review by the CAC under the applicable PRC cybersecurity laws and regulations with respect to the business operations of our PRC subsidiaries, because we or our PRC subsidiaries do not qualify as a critical information infrastructure operator or internet platform operator, or have conducted any data processing activities that affect or may affect national security, or hold personal information of more than one million users. However, as PRC governmental authorities have significant discretion in interpreting and implementing statutory provisions and there remains significant uncertainty in the interpretation and enforcement of relevant PRC cybersecurity laws and regulations, if the PRC regulatory authorities take a position contrary to ours, we cannot assure you that the business operation of ours or any of our PRC Subsidiaries will not be deemed to be subject to PRC cybersecurity review requirements under the 2022 Cybersecurity Review Measures or the Network Data Regulation as a critical information infrastructure operator, data processor or an internet platform operator that is engaged in data processing activities that affect or may affect national security or holds personal information of more than one million users, nor can we assure you that we or our PRC Subsidiaries would be able to pass such review. If we or our PRC subsidiaries fail to receive any requisite permission or approval from the CAC for our business operations, or the waiver for such permission or approval, in a timely manner, or at all, or inadvertently conclude that such permission or approval is not required, or if applicable laws, regulations or interpretations change and obligate us to obtain such permission or approvals, we may be subject to increased compliance costs, fines, disruption or even suspension of business, revocation of business licenses or other penalties, as well as reputational damage or legal proceedings or actions against us, which may have a material adverse effect on our business, financial condition or results of operations. Any of the foregoing events may also significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless. In addition, we could become subject to enhanced cybersecurity review or investigations launched by PRC regulators in the future pursuant to new laws, regulations or policies, which may increase our costs for compliance and divert our management’s attention. Any failure or delay in the completion of the cybersecurity review procedures or any other non-compliance with applicable laws and regulations may result in fines, disruption or even suspension of business, revocation of business licenses or other penalties, as well as reputational damage or legal proceedings or actions against us, which may have a material adverse effect on our business, financial condition or results of operations.

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***Our securities may be delisted under the Holding Foreign Companies Accountable Act if the PCAOB is unable to inspect auditors with presence in China in future years, and the delisting of our securities, or the threat of their being delisted, may materially and adversely affect the value of your investment.***

The HFCAA was enacted on December 18, 2020 and has been subsequently amended. The HFCAA states if the SEC determines that a U.S. listed company has filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for two consecutive years, the SEC shall prohibit its securities from being traded on a national securities exchange or in the over-the-counter trading market in the United States.

Our consolidated financial statements for the fiscal years ended March 31, 2023 and 2024 contained in this Annual Report, have been audited by our former auditor Wei, Wei & Co., LLP (“WW&C”), an independent registered public accounting firm that is headquartered in the United States. WW&C is a firm registered with the PCAOB and is required by the United States laws to undergo regular inspections by the PCAOB to assess its compliance with the laws of the U.S. and professional standards. While WW&C has been inspected by the PCAOB on a regular basis, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities in China according to Article 177 of the PRC Securities Law. 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 in China to the PCAOB, an overseas securities regulator under the PRC Securities Law. As a result, the audit working papers of the financial statements for the fiscal years ended March 31, 2023 and 2024 in this Annual Report may not be inspected by the PCAOB, since the audit work was carried out by WW&C with the collaboration of their China-based offices and the PCAOB has not obtained such requisite approval. Our consolidated financial statements for the fiscal year ended March 31, 2025 contained in this Annual Report have been audited by our current auditor, Grant Thornton Zhitong Certified Public Accountants LLP (“Grant Thornton”). Grant Thornton is located in mainland China, a jurisdiction where the PCAOB was historically unable to conduct inspections and investigations completely before 2022. The trading of our securities may be prohibited and such securities may be delisted from Nasdaq or any other U.S. stock exchange under the HFCAA if the PCAOB is unable to inspect auditors with presence in China. The prohibition of trading of our securities and the delisting of the securities, or the threat of their being prohibited or delisted, may cause the value of such securities to significantly decline or, in extreme cases, become worthless.

On March 24, 2021, the SEC adopted interim final rules relating to the implementation of certain disclosure and documentation requirements of the HFCAA. On December 2, 2021, the SEC adopted amendments to finalize such rules, which include requirements to disclose information, including the auditor name and location, the percentage of shares of the issuer owned by governmental entities, whether governmental entities in the applicable foreign jurisdiction with respect to the auditor has a controlling financial interest with respect to the issuer, the name of each official of the Chinese Communist Party who is a member of the board of the issuer, and whether the articles of incorporation of the issuer contains any charter of the Chinese Communist Party. These amendments also establish procedures the SEC will follow in identifying issuers and prohibiting trading by certain issuers under the HFCAA, including that the SEC will identify an issuer as a “Commission-identified Issuer” if the issuer has filed an annual report containing an audit report issued by a registered public accounting firm that the PCAOB has determined it is unable to inspect or investigate completely, and will then impose a trading prohibition on an issuer after it is identified as a Commission-Identified Issuer for two consecutive years.

On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong without the approval of the Chinese authorities, including our current auditor, Grant Thornton Zhitong Certified Public Accountants LLP. We are required to comply with these rules if the SEC identifies us as having a “non-inspection” year by evaluating the annual report we file, in which it will identify the auditor who provide opinions related to the financial statements presented in the annual report, the location where the auditor’s report has been issued and the PCAOB ID number of such audit firm or branch. If we have two consecutive non-inspection years, the SEC will implement the trading prohibition of our securities through stop orders, and the exact timeline for when the SEC will delist an issuer after two consecutive non-inspection years remains imprecise. Our securities could be prohibited from trading in the United States if we are identified as a Commission-identified Issuer for two consecutive years.

In March 2022, the SEC issued its first “conclusive list of issuers identified under the HFCAA” indicating that those companies are now formally subject to the delisting provisions if they remain on the list for two consecutive years. 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 determinations 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 conduct inspections of PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong is subject to uncertainties and depends on a number of factors out of our and our auditor’s control. The PCAOB may continue to demand complete access in mainland China and Hong Kong, resume regular inspections 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.

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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 our securities could be adversely affected. If our auditor is unable to be inspected or it is unable to meet the PCAOB inspection requirement in time in future years, including retain a registered public accounting firm that the PCAOB is able to inspect, we would be identified as a “Commission-identified Issuer” and be delisted from Nasdaq upon the expiration of the applicable years of non-inspection under the HFCAA and our securities will not be permitted for trading “over-the-counter” either. If our securities are prohibited from trading in the United States, there is no certainty that we will be able to list on a non-U.S. exchange or that a market for our shares will develop outside of the United States. The delisting would substantially impair your ability to sell or purchase our securities when you wish to do so, and the risk and uncertainty associated with delisting would have a negative impact on the price of our securities. In addition, the delisting would 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, financial condition, and prospects. If our securities are delisted from Nasdaq and are prohibited from trading in the over-the-counter market in the United States, there is no certainty that we will be able to list on a non-U.S. exchange or that a market for our securities will develop outside of the United States.

***PRC governmental authorities’ significant oversight and discretion over our business operation could result in a material adverse change in our operations following the Business Combination and the value of our securities and our securities following the Business Combination.***

PRC governmental authorities have significant oversight and discretion over our business operations in China and may seek to intervene or influence such operations at any time the government deems appropriate to further its regulatory, political and societal goals, which could result in a material adverse change in our operations and/or the value of our securities. In addition, the PRC governmental authorities may also exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers. Any such action could result in a material change in our operations, significantly limit or completely hinder the value of our securities and our ability to offer or continue to offer securities to investors, and cause the value of such securities to significantly decline or be worthless. Furthermore, occurrences of incidents or scandals within other companies in the same or similar industries that attract government scrutiny or national level attention, and the implementation of industry-wide regulations directly targeting our operations could cause the value of our securities and our securities to significantly decline.

***Changes in China’s economic, political or social conditions or government policies could have a material adverse effect on our business and operations.***

We conduct a substantial portion of our business in China, including, manufacturing and sales of YSJATM rabies vaccines and certain R&D activities. As such, our business, financial condition, results of operations and prospects may be influenced to a significant degree by political, economic, social and other conditions in China, including, among others, regulatory environment, overall economic growth, level of urbanization and level of per capita disposable income. The Chinese economy differs from the economies of most developed countries in many respects, including the level of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the Chinese government has implemented various changes, a significant portion of the productive assets in China are owned by the government, and the Chinese government continues to play a significant role in regulating industry development by setting industrial policies. The Chinese government also exercises significant control over China’s economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing different treatment to particular industries or companies.

While the Chinese economy has experienced significant growth over past decades, growth has been uneven, both geographically and among various sectors of the economy. Any adverse changes in economic conditions in China, the policies of the Chinese government or the laws and regulations in China could have a material adverse effect on the overall economic growth of China. Such developments may lead to a reduction in demand for our marketed product or product candidates in the future and materially and adversely affect our business, financial condition and results of operations. In addition, stimulus measures designed to boost the Chinese economy may contribute to higher inflation, which could adversely affect our results of operations and financial condition.

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***A severe or prolonged downturn in the PRC or global economy and political tensions between the United States and China could materially and adversely affect our business and financial condition.***

The global macroeconomic environment is facing challenges, including the end of quantitative easing by the U.S. Federal Reserve, the economic slowdown in the Eurozone since 2014 and uncertainties over the impact of Brexit. The Chinese economy has shown slower growth compared to the previous decade since 2012 and the trend may continue. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world’s leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa, the wars and conflicts in Ukraine and Russia, which have resulted in market volatility.

If we plan to expand our business internationally and do cross-border business in the future, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our products and product candidates, impact our competitive position, or prevent us from being able to conduct business in certain countries. If any new tariffs, legislation, or regulations are implemented, or if existing trade agreements are renegotiated, such changes could adversely affect our business, financial condition, and results of operations. In particular, there have been heightened tensions in international economic relations between the United States and China. The U.S. government recently imposed, and recently proposed to impose additional, new, or higher tariffs on certain products imported from China to penalize China for what the U.S. government characterizes as unfair trade practices. In 2025, trade frictions between China and the United States escalated significantly, with the U.S. imposing multiple rounds of tariffs on Chinese goods. As of April 16, 2025, the highest tariff rate in the current round imposed by the U.S. on certain Chinese products reached up to 245%. In May 2025, both sides issued the Joint Statement of the China-U.S. Economic and Trade Talks in Geneva, agreeing to suspend certain tariff increases for a period of 90 days and reduce the effective tariff rate to 10%. While tariff pressures have been alleviated in the short term, significant uncertainties remain regarding the long-term political dynamics between the two nations. However, the potential negative impact on the general economic, political, and social environment resulting from international trade tensions and their possible escalation could adversely affect our business, financial condition, and results of operations.

***Our business operations are subject to various PRC laws and regulations, the interpretation and enforcement of which involve significant uncertainties as the PRC legal system is evolving rapidly.***

The PRC legal system is a civil-law system based on written statutes. Unlike the common-law system, prior court decisions under the civil-law system may be cited for reference but have limited precedential value, which has led to uncertainty and inconsistency in the interpretation and enforcement of many laws. Uncertainties also exist with respect to new legislation or proposed changes in the PRC regulatory requirements as the PRC legal system is evolving rapidly. The interpretations of many laws and regulations may contain inconsistencies, and the enforcement of these laws, regulations and rules involves uncertainties. In addition, laws and regulations can change quickly with limited advance notice. From time to time, we may have to resort to administrative and court proceedings to enforce our legal rights. Because PRC administrative and court authorities have significant discretion in interpreting and implementing statutory provisions and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy. Such uncertainty towards the contractual, property and procedural rights and legal obligations could adversely affect our business and impede our ability to grow their business. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us.

***PRC regulations relating to offshore investment activities by PRC residents may subject our PRC resident shareholders, beneficial owners and PRC subsidiaries to liability or penalties, limit their ability to inject capital into our PRC subsidiaries, limit our PRC subsidiaries’ ability to increase their registered capital or distribute profits to us or otherwise adversely affect it.***

In July 2014, the SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents’ Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles (“SAFE Circular 37”). SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities, as well as foreign individuals that are deemed PRC residents for foreign exchange administration purposes) to register with the SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 further requires the SAFE registrations be updated in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as a change in its name, operation term and PRC resident shareholder, an increase or decrease of capital contribution, share transfer or exchange by PRC resident individuals, or mergers or divisions.

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In September 2014, MOFCOM promulgated the Measures for the Administration of Overseas Investment. In December 2017, the NDRC further promulgated the Administrative Measures of Overseas Investment of Enterprises, which became effective in March 2018. Pursuant to these regulations, any outbound investment of PRC enterprises in a non-sensitive area or industry is required to be filed with MOFCOM and the NDRC or their local branches.

We requested that all of our current shareholders and beneficial owners who, to their and our knowledge, are PRC residents complete the foreign exchange registrations and that those who, to their and our knowledge, are PRC enterprises comply with outbound investment related regulations. However, we may not be informed of the identities of all the PRC residents and PRC enterprises holding direct or indirect interest in us, and they and we cannot provide any assurance that these PRC residents and PRC enterprises will comply with their and our request to make or obtain the applicable registrations or continuously comply with all the requirements under SAFE Circular 37 or other related rules and the outbound investment related regulations. Failure by such shareholders or beneficial owners to comply with SAFE and outbound investment related regulations, or our failure 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 and prospects.

Furthermore, as these foreign exchange and outbound investment related regulations are relatively new and their interpretation and implementation is constantly evolving, it is uncertain how these regulations, and any future regulations concerning offshore or cross-border investments and transactions, will be interpreted, amended and implemented by the relevant government authorities. For example, we may be subject to a more stringent review and approval process with respect to our foreign exchange activities, such as remittance of dividends and foreign-currency-denominated borrowings, which may adversely affect our financial condition and results of operations. Due to the complexity and constantly changing nature of the regulations related to foreign exchange and outbound investment, as well as the uncertainties involved, we cannot assure you that we have complied or will be able to comply with all applicable foreign exchange and outbound investment related regulations. In addition, if we decide to acquire a PRC domestic company, we cannot assure you that we or our owners, as the case may be, will be able to obtain the necessary approvals or complete the necessary filings and registrations required by the foreign exchange regulations. This may restrict our ability to implement our acquisition strategy and could adversely affect our business and prospects.

***Our PRC subsidiaries are subject to restrictions on paying dividends or making other payments to our offshore holding companies, including us, which may restrict their ability to satisfy liquidity requirements.***

We are a holding company incorporated in the Cayman Islands. Payment of dividends by our PRC subsidiaries is an important source of support for us to meet their financing needs, and such payment is subject to various restrictions. Current PRC regulations permit the PRC subsidiaries to pay dividends to their offshore holding companies only out of their accumulated after-tax profits upon satisfaction of relevant statutory condition and procedures, if any, determined in accordance with Chinese accounting standards and regulations. In addition, each of our PRC subsidiaries is required to set aside at least 10% of its after-tax profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of its registered capital. In addition, the PRC Enterprise Income Tax Law and its implementation rules provide that withholding tax at the rate of 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. Furthermore, if our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us which may restrict their offshore holding companies’ ability to satisfy our liquidity requirements.

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

The value of the Renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in the political and economic conditions in China and China’s foreign exchange policies. On July 21, 2005, the PRC government changed its decade-old policy of pegging the value of the Renminbi to the U.S. dollar. On November 30, 2015, the Executive Board of the International Monetary Fund completed the regular five-year review of the basket of currencies that make up the Special Drawing Right (the “SDR”) and decided that, from October 1, 2016, Renminbi would be determined to be a freely usable currency and will be included in the SDR basket. Since June 2010, the Renminbi has fluctuated significantly against the U.S. dollar. It is difficult to predict how market forces or policies by the PRC or U.S. government may impact the exchange rate between the Renminbi and the U.S. dollar in the future. With the development of the foreign exchange market and progress towards interest rate liberalization and Renminbi internationalization, the PRC government may in the future announce further changes to the exchange rate system, and we cannot assure you that the Renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future.

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Significant revaluation of the Renminbi may materially and adversely affect our revenues, earnings and financial position, and the value and trading price of, and any dividends payable on, our securities in U.S. dollars. The appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount that would be received from the conversion to the extent that needs to be converted U.S. dollars into Renminbi for capital expenditures and working capital and other business purposes. Conversely, a significant depreciation of the Renminbi against the U.S. dollar may significantly reduce the U.S. dollar equivalent of the earnings, which in turn could adversely affect the price of our securities and have a negative effect on the U.S. dollar amount available to us for the purpose of making payments for dividends on our securities, royalties, strategic acquisitions or investments or for other business purposes.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, no hedging transactions in an effort to reduce our exposure to foreign currency exchange risk were contracted. While we may enter into hedging transactions in the future, the availability and effectiveness of these transactions may be limited, and we may not be able to adequately hedge the 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.

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

Under PRC laws and regulations, loans by us to our PRC subsidiaries to finance their operations shall not exceed certain statutory limits and must be registered with the local counterpart of the SAFE, and any capital contribution from us or us to our PRC subsidiaries is required to be registered, filed with or reported to the competent PRC governmental authorities. Currently, there is no statutory limit to the amount of funding that it can provide to our PRC subsidiaries through capital contributions, because there is no statutory limit on the amount of registered capital for our PRC subsidiaries and it is allowed to make capital contributions to our PRC subsidiaries by subscribing for their registered capital, provided that the PRC subsidiaries complete the relevant filing, registration and reporting procedures. According to relevant PRC regulations on foreign-invested enterprises, capital contributions to the relevant PRC subsidiaries are required to be registered with the SAMR or its local counterpart and a local bank authorized by SAFE, and reported to MOFCOM’s local counterpart.

***Foreign exchange controls may limit our ability to effectively utilize our revenues and proceeds generated or financed outside China and adversely affect the value of your investment.***

The PRC government imposes foreign exchange controls on the convertibility of the Renminbi and, in certain cases, the remittance of currency out of China. We receive substantially all of our revenues in Renminbi. Under the existing exchange restrictions, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of mainland China to pay capital expenses, such as the repayment of loans denominated in foreign currencies. As a result, we need to obtain requisite approval or registration to use cash generated from the operations of our PRC subsidiaries to pay off their respective debt in a currency other than Renminbi owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than Renminbi. The PRC government may also at our discretion restrict access to foreign currencies for current account transactions in the future. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends to you or fulfill other payment obligations in foreign currencies or fund any future operations that we may have outside of mainland China with foreign currencies.

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In addition, under the Circular on Reforming the Management Approach Regarding the Foreign Exchange Capital Settlement of Foreign-Invested Enterprises (“FIEs”) and the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, FIEs are prohibited from using Renminbi funds converted from their foreign exchange capital for expenditures beyond their business scopes or using such Renminbi funds to provide loans to persons other than their affiliates, unless within their business scope.

Any foreign loan procured by our PRC subsidiaries is also required to be registered with the SAFE or its local branches or be filed with the SAFE in its information system, and each of our PRC subsidiaries may not procure loans which exceed either (1) the amount of the difference between their respective registered total investment amount and registered capital or (2) two and a half times, or the then-applicable statutory multiple, the amount of their respective audited net assets, calculated in accordance with PRC GAAP (the “Net Assets Limit”), at our election. Increasing the amount of the difference between their respective registered total investment amount and registered capital of the PRC subsidiaries might be subject to governmental approval and may require a PRC subsidiary to increase its registered capital at the same time. If we make a loan to a PRC entity based on its Net Assets Limit, the maximum amount that the offshore companies would be able to loan to the relevant PRC entity would depend on the relevant entity’s net assets and the applicable statutory multiple at the time of the calculation. As of the date of this Annual Report, the majority of our PRC subsidiaries have negative or very limited net assets, which prevents them from providing loans to them using the Net Assets Limit. Liaoning Yisheng, a subsidiary of ours with substantial net assets, was temporarily unable to secure credit lines from banks due to the ongoing legal proceedings in China. For additional information on litigation, see “Item 4. Information On the Company—Business Overview—Legal Proceedings and Compliance”. Any medium- or long-term loan to be provided by us or a foreign third party to the PRC subsidiaries must also be registered by and filed with the NDRC.

On October 23, 2019, SAFE further issued the Circular of the State Administration of Foreign Exchange on Further Promoting the Facilitation of Cross-Border Trade and Investment (“Circular 28”), which took effect on the same day. Circular 28 allows non-investment FIEs to use their capital funds to make equity investments in China as long as such investments do not violate the then effective negative list for foreign investments and the target investment projects are genuine and in compliance with laws. In addition, Circular 28 stipulates that qualified enterprises in certain pilot areas may use their capital income from registered capital, foreign debt and overseas listing, for the purpose of domestic payments without providing authenticity certifications to the relevant banks in advance for those domestic payments. As this circular is relatively new, there remains uncertainty as to its interpretation and application and any other future foreign exchange-related rules. Violations of these circulars could result in severe monetary or other penalties.

These PRC laws and regulations may significantly limit our ability to use Renminbi converted from the proceeds received outside China to fund the establishment of new entities in China by our PRC subsidiaries, and to invest in or acquire any other PRC companies through our PRC subsidiaries. Moreover, we cannot assure you that we will be able to complete the necessary registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans to our PRC subsidiaries, or future capital contributions by us to our PRC subsidiaries. If we fail to complete such registrations or obtain such approvals or if it is found to be in violation of any applicable laws with respect to foreign currency exchange, our ability to use the proceeds we received or expect to receive from our offshore offerings may be negatively affected and it may be subject to penalties, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

***The M&A Rules and certain other PRC regulations could make it more difficult for us to pursue growth through acquisitions in China.***

In China, the M&A Rules, established additional procedures and requirements that could make merger and acquisition activities involving the PRC by foreign investors more time-consuming and complex, including requirements in some instances that the in-charge government authority be notified and relevant approval shall be obtained 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 of the PRC requires that the in-charge government authority be notified in advance of any concentration of undertaking if certain thresholds are triggered. In light of the uncertainties relating to the interpretation, implementation and enforcement of the Anti-monopoly Law, we cannot assure you that the in-charge Anti- monopoly Law enforcement agency will not deem our past acquisition or investments to have triggered the filing requirement for anti-trust review. If we are found to have violated the Anti-monopoly Law for failing to file the notification of concentration and request for review, we could be, among others, subject to a fine of up to RMB5,000,000 if the concentration has no effect of eliminating the restricting competition, or a fine of not more than 10% of our sales amount in the previous year if the concentration has or may have the effect of eliminating or restricting competition, and the parts of the transaction causing the prohibited concentration could be ordered to be unwound, which may materially and adversely affect our business, financial condition and results of operations. In addition, under applicable laws, mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by MOFCOM, and any activities attempting to bypass a security review, including by structuring the transaction through a proxy or contractual control arrangement, are prohibited.

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In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

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

We assumed our share incentive plan and the outstanding awards. Pursuant to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, promulgated by the SAFE in 2012, grantees of our incentive share awards who are PRC citizens or who are non-PRC residents continuously residing in the PRC for a continuous period of no less than a year (excluding the foreign diplomatic personnel and representatives of international organizations) are required to register with the SAFE and complete certain other procedures through a domestic qualified agent and collectively retain an overseas entrusted institution to handle matters related to the exercise of stock options and the purchase and disposition of related equity interests after we have become an overseas listed company. Failure to comply with these SAFE requirements may subject these individuals to fines and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries and limit our PRC subsidiaries’ ability to distribute dividends to us.

The SAT has also issued certain circulars concerning equity incentive awards. Under these circulars, our employees in China who exercise share options or are granted restricted share units will be subject to PRC individual income tax. If our employees fail to pay or if we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax or other PRC governmental authorities.

***Your ability to effect service of legal process, enforce judgments or bring actions against us or certain of our officers and directors outside the U.S. will be limited and additional costs may be required.***

We are a Cayman Islands holding company that conducts substantial operations outside the United States. A majority of our officers and directors reside outside the United States, and a substantial portion of the assets of those persons are located outside of the United States. Therefore, it may be difficult or costly for you to effect service of process against us or our officers and directors within the U.S. In addition, we were advised by our PRC legal counsel that it is uncertain (1) whether and on what basis a PRC court would enforce judgment rendered by a court in the U.S. based upon the civil liability provisions of U.S. federal securities laws; and (2) whether an investor will be able to bring an original action in a PRC court based on U.S. federal securities laws. 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. As such, you may not be able to or may experience difficulties or incur additional costs to enforce judgments obtained in U.S. courts based upon the civil liability provisions of U.S. federal securities laws in China or bring original actions in China based on U.S. federal securities laws even if you are successful in bringing an action of this kind. Furthermore, any judgment obtained in the U.S. against us and these individuals may not be collectible within the United States.

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***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 the law of the Cayman Islands, we conduct substantially all of our operations and a majority of their respective directors and executive officers reside outside of the United States.***

We are a company incorporated in the Cayman Islands with limited liability, and we will continue to conduct a majority of our operations through certain of our subsidiaries, namely, Philippines Yisheng, Singapore LakeShore, Liaoning Yisheng and Beijing Yisheng, which are outside the United States. Substantially all of our assets are located outside of the United States. A majority of our officers and directors reside outside the United States and a substantial portion of the assets of those persons are located outside of the United States. As a result, it could be difficult or impossible for you to bring an action against the us or against these individuals outside of the United States in the event that you believe that your rights have been infringed upon under the applicable securities laws or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and of the PRC could render you unable to enforce a judgment against the relevant assets or the assets of the relevant directors and officers.

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

Shareholders of Cayman Islands exempted companies like the us have no general rights under Cayman Islands law to inspect corporate records or to obtain copies of lists of shareholders of these companies (save for the memorandum and articles of association, the register of mortgages and charges, and special resolutions of our shareholders). Our directors will have discretion under the Articles to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but we are not obliged to make them available to the 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. See “Item 10. Additional Information—B. Memorandum and Articles of Association—Inspection of Books and Records.”

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

As a result of all of the above, our shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a company incorporated in the United States.

***Inflation in China and increase in labor costs could negatively affect our profitability and growth.***

Economic growth in China has been accompanied by periods of high inflation, and the PRC government implemented various policies from time to time to control inflation, including imposing various corrective measures designed to restrict the availability of credit or regulate growth. High inflation in the future may cause the PRC government to once again impose controls on credit and/or price of commodities, or to take other actions, which could inhibit economic activities in China. Any action on the part of the PRC government that seeks to control credit and/or price of commodities may adversely affect our business operations, causing negative impact on our profitability and growth.

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Moreover, the significant economic growth in China has resulted in a general increase in labor costs and shortage of low-cost labor. Inflation may cause our production cost to continue to increase. If we are unable to pass on the increase in production cost to our customers, we may suffer a decrease in profitability and a loss of customers, and our results of operations could be materially and adversely affected. In addition, PRC entities are subject to stricter regulatory requirements in entering into labor contracts with their employees and paying various statutory employee benefits, including pensions, housing funds, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance to designated government agencies for the benefit of their employees. Pursuant to the PRC Labor Contract Law and its implementation rules, employers are subject to stricter requirements in signing labor contracts, minimum wages, overtime work, labor dispatch, paying remuneration, determining the term of employee’s probation and unilaterally terminating labor contracts. In the event we decide to terminate some of our employees or otherwise change their employment or labor practices, the PRC Labor Contract Law and its implementation rules may limit our ability to effect those changes in a desirable or cost-effective manner, which could adversely affect our business and results of operations. In addition, we need to apply for flexible working hours arrangement and comprehensive working hours scheme with relevant PRC authorities and comply with the requirements contained in the relevant approvals, or pay employees overtime work compensations in case we intend to ask our employees to work overtime. We might not be able to, in a timely manner or at all, obtain relevant approvals and fully comply with requirements therein, or pay the overtime work compensation according to relevant regulations.

Pursuant to the PRC laws and regulations, companies registered and operating in China are required to apply for social insurance registration and housing fund deposit registration within 30 days of their establishment and to pay different social insurance and housing provident funds for their employees. Recently, as the PRC government enhanced its enforcement measures relating to social insurance collection, we may be required to make up the contributions for our employees and may be further subjected to late fees payment and administrative fines, which may adversely affect our financial condition and results of operations.

As the interpretation and implementation of labor-related laws and regulations are still evolving, we cannot assure you that our employment practices have been and will be in compliance with labor-related laws and regulations in China in all material respects, which may subject us to labor disputes or government investigations and penalties. In addition, it may incur additional expenses in order to comply with such laws and regulations, which may adversely affect our business and profitability.

***We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law, and we may therefore be subject to PRC income tax on our global income.***

We are a holding company incorporated under the laws of the Cayman Islands and indirectly hold interests in a Hong Kong-incorporated subsidiary, which in turn hold interests in certain PRC subsidiaries following the consummation of the Business Combination. Pursuant to the EIT Law, effective in January 2008, as amended on lately December 29, 2018, and its implementation rules, dividends payable by a foreign-invested enterprise to its foreign corporate investors who are not deemed a PRC resident enterprise are subject to a 10% withholding tax, unless such foreign investor’s jurisdiction of incorporation has a tax treaty with the PRC that provides for a different withholding tax arrangement. Under the Arrangement between the Mainland of China and Hong Kong Special Administration Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Tax on Income (the “Tax Treaty”) which was promulgated by SAT and the Hong Kong government on August 21, 2006, such dividend withholding tax rate is reduced to 5% for dividends paid by a PRC resident enterprise to a Hong Kong-resident enterprise if such Hong Kong entity is a “beneficial owner” and such entity directly owns at least 25% of the equity interest of the PRC company. The Announcement on Issues Relating to “Beneficial Owner” in Tax Treaties, effective in April 2018, provides certain factors for the determination of “beneficial owner” status of a company under the Tax Treaty. If the PRC tax authorities determine that our Hong Kong subsidiary is not a “beneficial owner,” we may not be able to enjoy a preferential withholding tax of 5% and dividend payable by our PRC subsidiaries to our Hong Kong subsidiary will be subject to withholding tax at 10%.

The EIT Law and its implementation rules also provide that if an enterprise incorporated outside China has its “de facto management bodies” within China, such enterprise may be deemed a “PRC resident enterprise” for tax purposes and be subject to an enterprise income tax rate of 25% on its global incomes. “De facto management body” is defined as the body that has the significant and overall management and control over the business, personnel, accounts and properties of an enterprise. In April 2009, SAT promulgated a circular, known as Circular 82, and latest revised in December 2017, to clarify the certain criteria for the determination of the “de facto management bodies” for foreign enterprises controlled by PRC enterprises or PRC enterprise groups. Further to Circular 82, the SAT issued a bulletin, known as Bulletin 45, effective in September 2011 and lately amended on June 15, 2018, respectively to provide more guidance on the implementation of Circular 82 and clarify the reporting and filing obligations of such “Chinese-controlled offshore incorporated resident enterprises.” Although Circular 82 and Bulletin 45 explicitly provide that the above standards apply to enterprises that are registered outside China and controlled by PRC enterprises or PRC enterprise groups, these regulations may reflect SAT’s criteria for determining the tax residence of foreign enterprises in general.

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However, there are no official implementation rules regarding the determination of the “de facto management bodies” for foreign enterprises not controlled by PRC enterprises (including companies like us). Therefore, it remains unclear how the tax authorities will treat a case such as ours and our subsidiaries following the consummation of the Business Combination. However, if the PRC authorities were to subsequently determine, or any future regulation provides, that we should be treated as a PRC resident enterprise, we will be subject to the uniform 25% enterprise income tax on its global incomes. In addition, although the EIT Law provides that dividend payments between qualified PRC-resident enterprises are exempt from enterprise income tax, there is uncertainty to the detailed qualification requirements for this exemption and whether dividend payments by our PRC subsidiaries to us will meet such qualification requirements even if it is considered a PRC resident enterprise for tax purposes.

There remains significant uncertainty as to the interpretation and application of applicable PRC tax laws and rules by the PRC tax authorities, and the PRC tax laws, rules and regulations may also change. If there is any change to applicable tax laws and rules and interpretation or application with respect to such laws and rules, the value of your investment in our shares may be materially affected.

***We and our shareholders face uncertainties with respect to the Business Combination and other indirect transfers of equity interests in PRC resident enterprises.***

Under the SAT Bulletin 7, an “indirect transfer” of assets, including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be re-characterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of reducing, deferring or avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. According to SAT Bulletin 7, “PRC taxable assets” include assets attributed to an establishment in China, immovable properties in China, and equity investments in PRC resident enterprises. In respect of an indirect offshore transfer of assets of a PRC establishment, the relevant gain is to be regarded as effectively connected with the PRC establishment and therefore included in its enterprise income tax filing, and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to the immovable properties in China or to equity investments in a PRC resident enterprise, which is not effectively connected to a PRC establishment of a non-resident enterprise or otherwise provided in the SAT Bulletin 7, a PRC enterprise income tax at 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements, and the party who is obligated to make the transfer payments has the withholding obligation. There is uncertainty as to the implementation details of SAT Bulletin 7. If SAT Bulletin 7 was determined by the tax authorities to be applicable to some of our transactions involving PRC taxable assets, including the Business Combination, our offshore subsidiaries conducting the relevant transactions might be required to spend valuable resources to comply with SAT Bulletin 7 or to establish that the relevant transactions should not be taxed under SAT Bulletin 7.

On October 17, 2017, the SAT issued the Bulletin on Issues Concerning the Source-based Withholding of Enterprise Income Tax on Non-resident Enterprises, or Bulletin 37, which became effective on December 1, 2017. According to Bulletin 37, if the withholding agent fails to or is unable to withhold the income tax in accordance with the law, the tax authority may order the payment within a time limit, and non-resident enterprises shall declare and make the payment within such time limit required by the tax authority, and the non-resident enterprise will be deemed to have cleared its tax payment on time if it voluntarily declares and pays the tax before or within the time limit the tax authority orders it to do so. If the taxable income before withholding on a source-basis falls within the form of dividends or any equity investment gains, the date of triggering obligations to settle such tax payments is the date of actual payment of the dividends or other equity investment gains. In addition, on December 1, 2017, Bulletin 37 repealed the Notice of the SAT on Strengthening the Administration over Enterprise Income Tax on Income of Non-resident Enterprises from Equity Transfer and Notice of the SAT on Issuing the Interim Measures for the Administration of Source-based Withholding of the Enterprise Income Tax of Non-resident Enterprises issued by the SAT on December 10, 2009 and January 1, 2009, respectively.

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As a result, SAT Bulletin 7 could apply if the Business Combination did not have a reasonable business purpose and was carried out to evade PRC corporate income tax obligations. Although we believe SAT Bulletin 7 does not apply to the Business Combination, it is possible that PRC tax authorities would make an assessment that the Business Combination is subject to SAT Bulletin 7. If SAT Bulletin 7 were to apply to the Business Combination, there would be PRC 10% withholding tax imposed on any gain deemed, from a PRC tax perspective, to have been realized from the Business Combination. In addition, we and our respective non-PRC Shareholders may have the risk of being taxed for the disposition of our Shares and may be required to spend valuable resources to comply with SAT Bulletin 7 and SAT Bulletin 37 or to establish that we and our respective non-PRC Shareholders should not be taxed as an indirect transfer, which may have a material adverse effect on their results of operations and financial condition or the investment by non-PRC investors in our securities.

In addition, since we may pursue acquisitions, and may conduct acquisitions involving complex corporate structures, the PRC tax authorities may, at their discretion, adjust the capital gains or request that we submit additional documentation for their review in connection with any potential acquisitions, which may cause us to incur additional acquisition costs or delay our acquisition timetable.

***Dividends payable to our foreign investors and gains on the sale of our securities by foreign investors may become subject to PRC tax.***

Under the EIT Law and its implementation regulations issued by the State Council, a 10% PRC withholding tax is applicable to dividends payable to investors that are non-resident enterprises, which do not have an establishment or place of business in China or which have such establishment or place of business but the dividends are not effectively connected with such establishment or place of business, to the extent such dividends are derived from sources within China. Similarly, any gain realized on the transfer of ordinary shares by such investors is also subject to PRC tax at 10%, subject to any reduction or exemption set forth in applicable tax treaties or under applicable tax arrangements between jurisdictions, if such gain is regarded as income derived from sources within China. If we are deemed a PRC resident enterprise, dividends paid on our securities, and any gain realized from the transfer of our securities, would be treated as income derived from sources within China and would as a result be subject to PRC taxation. Furthermore, if we are deemed a PRC resident enterprise, dividends payable to individual investors who are non-PRC residents and any gain realized on the transfer of our securities by such investors may be subject to PRC tax at 20%, subject to any reduction or exemption set forth in applicable tax treaties or under applicable tax arrangements between jurisdictions. If we or any of our subsidiaries established outside China are considered a PRC resident enterprise, it is unclear whether holders of ordinary shares would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas. If dividends payable to its non-PRC investors, or gains from the transfer of our securities by such investors, are deemed as income derived from sources within China and thus are subject to PRC tax, the value of your investment in our securities may decline significantly.

***We face regulatory uncertainties in China that could restrict our ability to grant share incentive awards to our employees or consultants who are PRC citizens.***

Pursuant to the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in a Stock Incentive Plan of an Overseas Publicly-Listed Company issued by SAFE on February 15, 2012, or Circular 7, a qualified PRC agent (which could be the PRC subsidiary of the overseas-listed company) is required to file, on behalf of “domestic individuals” (both PRC residents and non-PRC residents who reside in China for a continuous period of not less than one year, excluding the foreign diplomatic personnel and representatives of international organizations) who are granted shares or share options by the overseas-listed company according to its share incentive plan, an application with SAFE to conduct SAFE registration with respect to such share incentive plan, and obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the share purchase or share option exercise. Such PRC individuals’ foreign exchange income received from the sale of shares and dividends distributed by the overseas listed company and any other income shall be fully remitted into a collective foreign currency account in China, which is opened and managed by the PRC domestic agent before distribution to such individuals. In addition, such domestic individuals must also retain an overseas entrusted institution to handle matters in connection with their exercise of share options and their purchase and sale of shares. The PRC domestic agent also needs to update registration with SAFE within three months after, among others, the overseas-listed company materially changes its share incentive plan, including making any new share incentive plans.

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We have a share incentive plan and assume the outstanding share incentive awards granted by us and may grant options in the future. As such, we, from time to time, need to apply for or update our registration with SAFE or its local branches on behalf of our PRC domestic employees or consultants who receive options or other equity-based incentive grants under our share incentive plan or material changes in our share incentive plan. However, we may not always be able to make applications or update the registration on behalf of our PRC domestic employees or consultants who hold any type of share incentive awards in compliance with Circular 7, nor can we ensure you that such applications or update of registration will be successful. If we or the participants of our share incentive plan who are PRC domestic individuals fail to comply with Circular 7, we and/or such participants of our share incentive plan may be subject to fines and legal sanctions, there may be additional restrictions on the ability of such participants to exercise their share options or remit proceeds gained from sale of their shares into China, and we may be prevented from further granting share incentive awards under our share incentive plan to our employees or consultants who are PRC domestic individuals.

***It may be difficult for overseas regulators to conduct investigation or collect evidence within China.***

Shareholder claims or regulatory investigation that are common in the United States generally are difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigations initiated outside China.

Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the PRC territory. While detailed interpretation of or implementation rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase the difficulties you face in protecting your interests. See also “—Your ability to effect service of legal process, enforce judgments or bring actions against, us or certain of our officers and directors outside the U.S. will be limited and additional costs may be required.”

***If the custodians or authorized users of our controlling non-tangible assets, including chops and seals, fail to fulfill their responsibilities, or misappropriate or misuse these assets, our business and operations may be materially and adversely affected.***

Under PRC law, legal documents for corporate transactions, including agreements and contracts such as the leases and sales contracts that our business relies on, 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 local branch of the market supervision administration.

To maintain the physical security of our chops and the chops of our PRC entities, we generally store them in secured locations accessible only by the authorized personnel of each of our PRC subsidiaries. Although we monitor such authorized personnel, there is no assurance such procedures will prevent all instances of abuse or negligence. Accordingly, if any of our authorized personnel misuse or misappropriate our corporate chops or seals, we could encounter difficulties in maintaining control over the relevant entities and experience significant disruption to our operations. If a designated legal representative obtains control of the chops in an effort to obtain control over any of our PRC subsidiaries, we would need to pass a new shareholder or board resolution to designate a new legal representative and we would need to take 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 to it, which could involve significant time and resources and divert management attention away from our regular business. 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.

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***Our Hong Kong subsidiary or any future operations in Hong Kong or Macau could become subject to more influence and/or control of the PRC government if the Hong Kong or Macau legal system becomes more integrated into the PRC legal system.***

Most national laws and regulations of the PRC are not directly applicable in Hong Kong or Macau, except for those listed in the Basic Law of the Hong Kong Special Administrative Region of the PRC or the Basic Law of the Macau Special Administrative Region of the PRC (the “Basic Laws”). However, such list of national laws and regulations that are applicable in Hong Kong or Macau can be expanded by amendment to the Basic Laws. There is no assurance that the Basic Laws will not be further amended to apply more PRC laws and regulations in Hong Kong, or that the PRC and/or Hong Kong or Macau government will not take other actions to promote the further integration of Hong Kong or Macau legal system into the PRC legal system. Although we do not have substantive business operations in Hong Kong and Macau and do not currently expect to have any substantive operations in these regions in the foreseeable future, we cannot assure you that our Hong Kong subsidiary or any future operations in Hong Kong or Macau will not be subject to more influence and/or control of the PRC government or even direct oversight or intervention from them if the Hong Kong or Macau legal system becomes more integrated into the PRC legal system, or if the regulators in Hong Kong or Macau adopt similar rules or policies through affirmative legislation or rulemaking within the scope of the authority conferred by the Basic Laws. As a result, we cannot assure you that our Hong Kong subsidiary or any future operations in Hong Kong or Macau will not be exposed to the similar regulatory and/or policy risks and uncertainties faced by our subsidiaries in China in the future.

**Risks Related to Ownership of the Ordinary Shares**

***We have been involved, and may continue to be involved, in claims, disputes, litigation, arbitration or other legal proceedings by or against Mr. Yi Zhang, the former chairperson of our board of directors and a principal shareholder of our Company.***

We have been involved, and may continue to be involved, in claims, disputes, litigation, arbitration or other legal proceedings by or against Mr. Yi Zhang, the former chairperson of our board of directors and a principal shareholder of our Company. These may concern issues relating to, among others, the removal of Mr. Yi Zhang as the chairperson of our board of directors and alleged misconduct and/or illegal activities of the Company caused by or under the control of Mr. Yi Zhang. For example, since December 2023, the Company has been involved in several legal proceedings in the Cayman Islands and China against Mr. Yi Zhang, his associates and/or entities controlled by Mr. Yi Zhang. See “Item 4. Information on the Company—B. Business Overview—Legal Proceedings and Compliance.” Any such claims, disputes or legal proceedings may divert our management team’s attention, result in substantial costs, disruption of our business operations, diversion of resources and material harm to our reputation.

***If the market price for our ordinary shares falls below US$1.00 for an extended period of time, our ordinary shares may be delisted from Nasdaq, which could affect the market price and liquidity for our ordinary shares and reduce our ability to raise additional capital.***

On October 24, 2023, Nasdaq notified us that we were not in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5450(a)(2) because the bid price of our ordinary shares closed below the $1.00 per share minimum bid price required for continued listing on Nasdaq for 31 consecutive trading days. The notice has no immediate effect on the listing of the Company’s Shares and they will continue to trade on Nasdaq. Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar days after receipt of notice, or until April 22, 2024, the closing bid price of the ordinary shares is at least $1.00 for a minimum of 10 consecutive business days, the Company will regain compliance with the minimum bid price requirement. On April 29, 2024, we received an extension of 180 calendar days from Nasdaq to regain compliance. On October 21, 2024, we received a written notice from Nasdaq, informing us that we had regained compliance with the minimum bid price requirement set forth under the Nasdaq Listing Rule 5550(a)(2) because the closing bid price of our ordinary shares had been $1.00 per share or greater for 11 consecutive business days, from October 4, 2024, to October 18, 2024.

However, we cannot guarantee similar events will not happen in the future. Any non-compliance with Nasdaq’s continued listing standards may be costly, divert management’s time and attention, and could have a material adverse effect on our business, reputation, financing, and results of operation. Further, if our ordinary shares are subject to potential delisting or are delisted due to our non-compliance of Nasdaq continued listing standards, we may face substantial decrease in trading of our ordinary shares, which will materially adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and may result in fewer business development opportunities.

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***The price of the ordinary shares may be volatile, and the value of the ordinary shares may continue to decline.***

We cannot predict the prices at which the ordinary shares will trade. The price of the ordinary shares may not bear any relationship to the market price at which the ordinary shares trade or to any other established criteria of the value of our business and prospects, and the market price of the ordinary shares may fluctuate substantially. In addition, the trading price of the ordinary shares is likely to be volatile and could be subject to fluctuations in response to various factors, some of which are beyond our control. These fluctuations could cause you to lose all or part of your investment in the ordinary shares as you might be unable to sell your shares at or above the price you paid. Factors that could cause fluctuations in the trading price of the ordinary shares include the following:

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|  | ● | actual or anticipated fluctuations in our financial condition or results of operations; |

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|  | ● | variance in our financial performance from expectations of securities analysts; |

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|  | ● | changes in the pricing of our products; |

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| --- | --- | --- |
|  | ● | changes in our projected operating and financial results; |

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| --- | --- | --- |
|  | ● | changes in laws or regulations applicable to our products and industry; |

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|  | ● | announcements by us or our competitors of significant business developments, acquisitions, strategic partnerships or new offerings; |

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|  | ● | sales of the ordinary shares by us or our shareholders as well as the exercise of options; |

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|  | ● | significant product recalls, regulatory investigations, disruptions to or other incidents involving our products; |

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|  | ● | our involvement in litigation; |

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|  | ● | conditions or advancements, breakthroughs, developments affecting the vaccine industries; |

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|  | ● | future sales of the ordinary shares by us or our shareholders; |

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|  | ● | changes in senior management or key personnel; |

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|  | ● | the trading volume of the ordinary shares; |

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|  | ● | changes in the anticipated future size and growth rate of our markets; |

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|  | ● | changes in market sentiment towards the healthcare or biopharmaceutical sector, or shifts in investment trends; |

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|  | ● | publication of research reports or news stories about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts; |

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|  | ● | changes in general economic, political, regulatory, market conditions; and |

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| --- | --- | --- |
|  | ● | other events or factors, including those resulting from war including the conflict between Russia and Ukraine, incidents of terrorism, global pandemics or responses to these events. |

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Any of these factors may result in large and sudden changes in the volume and price at which the ordinary shares will trade. The securities of some China-based companies that listed their securities in the United States have experienced significant volatility since their initial public offerings in recent years, including, in some cases, substantial declines in the trading prices of their securities. The trading performances of these companies’ securities after their offerings may affect the attitudes of investors towards Chinese companies listed in the United States in general, which consequently may impact the trading performance of the ordinary shares, regardless of our actual operating performance. In addition, any negative news or perceptions about inadequate corporate governance practices or fraudulent accounting, corporate structure or other matters of other Chinese companies may also negatively affect the attitudes of investors towards Chinese companies in general, including us, regardless of whether we have engaged in any inappropriate activities. In particular, the global financial crisis, the ensuing economic recessions and deterioration in the credit market in many countries have contributed and may continue to contribute to extreme volatility in the global stock markets.

Moreover, there have been recent instances of extreme stock price run-ups followed by rapid price declines and strong stock price volatility with a number of recent initial public offerings, particularly among companies with relatively smaller public floats. As we have a relatively small public float after our offering and as the date of this Annual Report, we may experience greater stock price volatility, including aggressive price run-ups and declines, lower trading volume and less liquidity, compared with companies with larger public floats. In particular, the ordinary shares may be subject to rapid and substantial price volatility, low volumes of trades and large spreads in bid and ask prices. Such volatility, including any stock run-up, may be unrelated to our actual or expected operating performance, financial condition or prospects, and industry, market or economic factors, which makes it difficult for prospective investors to assess such rapidly changing value of the ordinary shares. In addition, if the trading volumes of the ordinary shares are low, persons buying or selling in relatively small quantities may easily influence prices of the ordinary shares. This low volume of trades could also cause the price of the ordinary shares to fluctuate significantly, with large percentage changes in price occurring in any trading day session. Holders of the ordinary shares may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to such low-volume trading. As a result of such volatility, investors may experience losses on their investment in the ordinary shares. Such volatility also could adversely affect our ability to issue additional ordinary shares or other securities and our ability to obtain additional financing in the future, as well as our ability to retain key employees, many of whom have been granted equity incentives. Furthermore, the extreme volatility may confuse the public investors of the value of the ordinary shares, distort the market perception of the price of the ordinary shares, and our financial performance and public image, and negatively affect the long-term liquidity of the ordinary shares, regardless of our actual or expected operating performance.

In the past, shareholders of public companies have brought securities class action suits against companies following periods of instability in the market price of their securities. If we were involved in a class action suit, it could divert a significant amount of our management’s attention and other resources from our business and require us to incur significant expenses to defend the suit, which could harm our results of operations. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. Furthermore, the announcement or perception of such litigation could potentially harm our reputation and the market price of our ordinary shares. If a claim is successfully made against us, we may be required to pay significant damages or settlements, if we do not have enough insurance coverage to satisfy such judgements or settlements, which could have a material adverse effect on our results of operations and financial condition.

***A market for our securities may not develop or be sustained, which would adversely affect the liquidity and price of our securities.***

The price of our securities fluctuated significantly due to the market’s reaction to the Business Combination and general market and economic conditions. An active trading market for our securities following the Business Combination may never develop or, if developed, it may not be sustained. In addition, the price of our securities after the Business Combination can vary due to general economic conditions and forecasts, our general business condition and the release of our financial reports. Additionally, if our securities become delisted from Nasdaq and are quoted on the OTC Bulletin Board (an inter-dealer automated quotation system for equity securities that is not a national securities exchange) or the combined company’s securities are not listed on Nasdaq and are quoted on the OTC Bulletin Board, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq, NYSE or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

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***Provisions in the Articles could discourage, delay or prevent a change of our control and may affect the trading price of the ordinary shares.***

Some provisions of the Articles may discourage, delay or prevent a change in our control of or management that shareholders may consider favorable. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board. However, these provisions could also have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of the ordinary shares that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that shareholders may otherwise deem to be in their best interests.

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|  | ● | The Articles only permit our shareholders together holding at least 10% of voting power of all the then outstanding ordinary shares as being entitled to do so to requisition a general meeting. |

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|  | ● | The Articles require the affirmative vote of the holders of at least two-thirds in voting power of all the then outstanding ordinary shares as being entitled to do so to pass any special resolution, which special resolution is required to, among others, amend the memorandum and articles of association or approve a merger. |

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|  | ● | Under the Articles, the number of directors shall be not less than three directors (or such greater number as may be approved by special resolution upon an amendment and/or restatement of the Articles). The directors shall be appointed and removed by ordinary resolution of the shareholders (except with regard to the removal of the Chairperson, who may be removed from office by two-thirds in voting power of all the then outstanding ordinary shares as being entitled to do so to pass a special resolution). |

In addition, these provisions may make it difficult and expensive for a third party to pursue a tender offer, change in control or takeover attempt that is opposed by our management or our Board. Shareholders who might desire to participate in these types of transactions may not have an opportunity to do so, even if the transaction is favorable to shareholders. These anti-takeover provisions could substantially impede the ability of shareholders to benefit from a change in control or change our management and our Board and, as a result, may adversely affect the market price of the ordinary shares and your ability to realize any potential change of control premium.

***The warrant agreement relating to the Warrants provides we agree that any action, proceeding or claim against us arising out of or relating in any way to such agreement will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and that we irrevocably submit to such jurisdiction, which will be the exclusive forum for any such action, proceeding or claim. This exclusive forum provision could limit the ability of holders of the Warrants to obtain what they believe to be a favorable judicial forum for disputes related to such agreement.***

In connection with the Business Combination, we entered into a Warrant Assignment Agreement pursuant to which SPAC assigned to us all of its rights, title, interests, and liabilities and obligations in and under the Warrant Agreement, dated June 8, 2021, by and between SPAC and Continental Stock Transfer & Trust Company. The Warrant Assignment Agreement provides that any action, proceeding or claim against us arising out of or relating in any way to such agreement, except for claims for which the federal courts have exclusive jurisdiction, such as lawsuits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, shall be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, which will be the exclusive forum for any such action, proceeding or claim.

The exclusive forum provision in the Warrant Assignment Agreement may limit the ability of holders of the Warrants to bring a claim in a judicial forum that it finds favorable for disputes related to the Warrant Assignment Agreement, which may discourage such lawsuits against us and our directors or officers. Alternatively, if a court were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

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***If we do not meet the expectations of equity research analysts, if they do not publish research or reports about our business or if they issue unfavorable commentary or downgrade the ordinary shares, the price of the ordinary shares could decline.***

The trading market for the ordinary shares will rely in part on the research and reports that equity research analysts publish about us and our business. The analysts’ estimates are based upon their own opinions and are often different from our estimates or expectations. These analysts make projections based on their independent opinions, which may differ from our internal estimates or expectations. If our actual results of operations do not meet these projections, or if analysts revise their estimates downwards, the price of our ordinary shares could decline significantly. Moreover, our reputation and the price of our ordinary shares could decline if one or more securities analysts downgrade the ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Furthermore, in some instances, equity research analysts may publish opinions or estimates about our business that we believe are incorrect or misleading. Rectifying these misperceptions could require significant time and resources, which may distract our management from other strategic initiatives. Despite our efforts, we may not be able to correct these misperceptions effectively, which could negatively impact the perception of our company and harm our stock price.

***Our issuance of additional share capital in connection with financings, acquisitions, investments, our equity incentive plans or otherwise will dilute all other shareholders.***

We expect to issue additional share capital in the future that will result in dilution to all other shareholders. We expect to grant equity awards to employees and directors under our equity incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire, make investments in or engage in strategic partnerships with companies, solutions or technologies and issue equity securities to pay for any such acquisition, investment or partnership. On February 7, 2024, we entered into a share purchase agreement with Apex Prospect Limited, a Cayman Islands exempted company, relating to the offer and sale of 95,269,762 ordinary shares for a total purchase price of US$40 million in a private placement transaction. On July 8, 2025, we entered into a Share and Warrant Purchase Agreement with Crystal Peak Investment Inc., a limited liability company incorporated under the laws of the British Virgin Islands, for the sale of 16,987,542 ordinary shares and 16,987,542 detachable warrants in a private placement transaction at a total consideration of US$15 million. Subsequently, on July 9, 2025, these warrants were fully exercised on a cashless basis, resulting in the issuance of 4,033,790 ordinary shares, which were formally recorded and made effective on July 11, 2025. Any such issuances of additional share capital may cause shareholders to experience significant dilution of their ownership interests and the per share value of the ordinary shares to decline.

***We are an emerging growth company and may take advantage of certain reduced reporting requirements.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, and we may take advantage of certain exemptions from various requirements applicable to other public companies that are not emerging growth companies including, most significantly, not being required to comply with the auditor attestation requirements of Section 404 of Sarbanes-Oxley Act of 2002 for so long as we are an emerging growth company. 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.

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

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

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|  | ● | the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current re-ports on Form 8-K; |

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|  | ● | the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act; |

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|  | ● | the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and |

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|  | ● | the selective disclosure rules by issuers of material nonpublic information under Regulation FD. |

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

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

As a foreign private issuer, 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. In the future, we would lose our foreign private issuer status if (1) more than 50% of our outstanding voting securities are owned by U.S. residents and (2) a majority of our directors or executive officers are U.S. citizens or residents, or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. If we lose our foreign private issuer status, 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 corporate governance requirements under the listing rules of Nasdaq. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer.

***As an exempted company incorporated in the Cayman Islands, we have elected to follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq’s corporate governance requirements; these practices may afford less protection to shareholders.***

As a Cayman Islands exempted company that is listed on Nasdaq, we are subject to the Nasdaq listing standards. For example, Section 5605(b)(1), Section 5605(c)(2) and Section 5635(c) of the Nasdaq Listing Rules require listed companies to have, among other things, a majority of our board members to be independent, an audit committee of at least three members and shareholders’ approval on adoption of equity incentive awards plans.

However, the Nasdaq rules permit a foreign private issuer like us to follow the corporate governance practices of our home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards. For example, under Cayman Islands law we are not required to (i) have a majority of independent directors serve on our board of directors, (ii) have regularly scheduled meetings at which only independent directors are present; (iii) have a compensation committee composed entirely of independent directors, (iv) have a nominating committee composed entirely of independent directors, (v) hold annual meeting of shareholders within one year after the end of a fiscal year, (vi) obtain shareholders’ approval prior to the issuance of securities when the issuance or potential issuance will result in a change of control of the Company and (vii) obtain shareholders’ approval prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees, or consultants, subject to certain exceptions. We have elected to follow home country practices in lieu of each of the foregoing corporate governance requirements under the Nasdaq Listing Rules. See “Item 16G. Corporate Governance.” Since we have chosen to follow certain home country practice, our shareholders may be afforded less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards.

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***We are a “controlled company” within the meaning of the Nasdaq listing rules and, as a result, may rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.***

We are a “controlled company” as defined under the Nasdaq corporate governance rules because Ms. Huaqin Xue controls 51.01% of the total voting power of all issued and outstanding ordinary shares. Ms. Xue currently exercises voting and dispositive control over the ordinary shares registered in the name of Crystal Peak Investment Inc., a limited liability company incorporated under the laws of the British Virgin Islands. On July 8, 2025, Crystal Peak entered into a Share and Warrant Purchase Agreement with us, pursuant to which we sold 16,987,542 ordinary shares and 16,987,542 detachable warrants in a private placement transaction for a total consideration of US$15 million. Subsequently, on July 9, 2025, these warrants were fully exercised on a cashless basis by Crystal Peak, resulting in the issuance of 4,033,790 ordinary shares, which were formally recorded and made effective on July 11, 2025. Crystal Peak Investment Inc. is a wholly owned subsidiary of Crystal Peak Holdings Inc (“Crystal Holdings”). Ms. Huaqin Xue is a director of both Crystal Peak and Crystal Holdings and is the sole shareholder of Crystal Holdings. Based on the foregoing, Ms. Xue is deemed to be the beneficial owner of these shares. In addition, pursuant to the Share and Warrant Purchase Agreement, Ms. Xue is restricted from directly or indirectly causing any changes in the composition of the Board or senior management, including the election and appointment of directors and officers, so long as she holds any of our equity securities. However, Ms. Xue retains the ability to influence certain of our corporate actions by virtue of her majority voting power. See “— *Our controlling shareholder will have considerable influence over us and certain of our corporate matters*” below for more details. In addition, for so long as we remain a controlled company, we are permitted to elect to rely on, and may rely on, certain exemptions from corporate governance rules, including an exemption from the rule that a majority of our board of directors must be independent directors. We rely on the exemption available for foreign private issuers to follow our home country governance practices. See “—Risks Related to Ownership of the ordinary shares—As an exempted company incorporated in the Cayman Islands, we have elected to follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq’s corporate governance requirements; these practices may afford less protection to shareholders.” If we cease to be a foreign private issuer or if we cannot rely on the home country governance practice exemptions for any reason, we may decide to invoke the exemptions available for a controlled company as long as we remain a controlled company. As a result, you will not have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements.

***If we fail to remediate our material weaknesses and implement and maintain an effective system of internal control over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud.***

We are a company with limited accounting personnel and other resources to address our internal control over financial reporting. We qualified as an “emerging growth company” pursuant to the Jumpstart Our Business Startups Act of 2012, as amended as of March 31, 2024. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company’s internal control over financial reporting (“ICFR”).

However, in connection with the audit of our consolidated financial statements as of and for the fiscal year ended March 31, 2025, we identified two material weaknesses 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 deficiencies, in ICFR, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidate financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified relate to (1) a lack of sufficient qualified personnel in the accounting and financial reporting process who is knowledgeable of U.S. GAAP and pertinent SEC reporting requirements, and (2) a lack of policies and procedures to ensure timely account reconciliation and analysis, review and detection of errors or inaccuracies in the consolidated financial statements and to enable adequate and sufficient disclosure in compliance with SEC reporting requirements.

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To remediate our identified material weaknesses, we are in the process of implementing a number of measures to improve our ICFR. See “Item 15. Controls and Procedures—Internal Control Over Financial Reporting.” The implementation of these measures, however, may not fully address the material weaknesses identified in our ICFR, and we cannot conclude that it has been fully remedied. Our failure to correct the material weaknesses or our failure to discover and address any other material weaknesses or deficiencies could result in inaccuracies in our financial statements and impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis**.** Moreover, ineffective ICFR could significantly hinder our ability to prevent fraud.

We are a public company in the United States subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we include a report of management assessment on our internal control over financial reporting in our annual report on Form 20-F. Our management has concluded that our internal control over financial reporting was ineffective as of March 31, 2025. Our management may continue to conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report concluding that our internal control over financial reporting is ineffective 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 we are a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other material weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to implement adequate measures to remediate our existing material weaknesses, 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. If we fail to achieve and maintain an effective internal control environment, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations, and lead to a decline in the trading price of the ADSs. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements for prior periods.

***As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in us and, as a result, the value of the ordinary shares.***

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our ICFR as of the end of the fiscal year that coincides with the filing of our second annual report on Form 20-F. This assessment will need to include disclosure of any material weaknesses identified by our management in our ICFR. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our ICFR in our first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company.”

We current control and any new controls that we develop may become inadequate because of changes in conditions in our business. In addition, changes in accounting principles or interpretations could also challenge our internal controls and require that we establish new business processes, systems and controls to accommodate such changes. Additionally, if these new systems, controls or standards and the associated process changes do not give rise to the benefits that we expect or do not operate as intended, it could materially and adversely affect our financial reporting systems and processes, our ability to produce timely and accurate financial reports or the effectiveness of ICFR. Moreover, our business may be harmed if we experience problems with any new systems and controls that result in delays in their implementation or increased costs to correct any post-implementation issues that may arise.

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During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our ICFR, we will be unable to certify that our ICFR is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our ICFR in the future. Any failure to maintain ICFR could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our ICFR is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our ICFR, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of the ordinary shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our ICFR, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

The growth and expansion of our business places a continuous, significant strain on our operational and financial resources. Further growth of our operations to support our customer base, our information technology systems and our internal controls and procedures may not be adequate to support our operations. As we continue to grow, we may not be able to successfully implement requisite improvements to these systems, controls and processes, such as system access and change management controls, in a timely or efficient manner. Moreover, our rapid expansion may necessitate a significant increase in the workforce and require us to manage multiple relationships with various partners, customers, and vendors. This could place additional stress on our infrastructure and increase our management challenges, potentially disrupting our current operations. Our failure to improve our systems and processes, or their failure to operate in the intended manner, whether as a result of the growth of our business or otherwise, may result in our inability to accurately forecast our revenue and expenses, or to prevent certain losses. Moreover, the failure of our systems and processes could undermine our ability to provide accurate, timely and reliable reports on our financial and operating results and could impact the effectiveness of our internal control over financial reporting. In addition, our systems and processes may not prevent or detect all errors, omissions or fraud.

***As a result of our plans to expand operations, including to jurisdictions in which the tax laws may not be favorable, our tax rate may fluctuate, our tax obligations may become significantly more complex and subject to greater risk of examination by taxing authorities or we may be subject to future changes in tax law, the impact of which could adversely affect our after-tax profitability and financial results.***

Because we do not have a long history of operating at our present scale and have significant expansion plans, our effective tax rate may fluctuate in the future. Future effective tax rates could be affected by our operating results before taxes, changes in the composition of operating income and earnings in countries or jurisdictions with differing tax rates, including as we expand into additional jurisdictions, changes in the amount of our deferred tax assets and liabilities, changes in accounting and tax standards or practices, changes in tax laws, changes in the tax treatment of share-based compensation, and our ability to structure our operations in an efficient and competitive manner.

Due to the complexity of multinational tax obligations and filings, we may have a heightened risk related to audits, examinations or administrative appeals by taxing authorities. Outcomes from current and future tax audits, examinations or administrative appeals could have an adverse effect on our after-tax profitability and financial condition. Additionally, several tax authorities have increasingly focused attention on intercompany transfer pricing with respect to sales of products and services and the use of intangibles. Tax authorities could disagree with our intercompany charges, cross-jurisdictional transfer pricing or other matters and assess additional taxes. If we do not prevail in any such disagreements, our profitability may be affected.

Our after-tax profitability and financial results may also be adversely impacted by changes in the relevant tax laws and tax rates, treaties, regulations, administrative practices and principles, judicial decisions and interpretations thereof, in each case, possibly with retroactive effect. For example, the Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting entered into force in 2018 among the jurisdictions that have ratified it. Additionally, many countries and organizations, such as the Organization for Economic Cooperation and Development, are also actively considering changes to existing tax laws or have proposed or enacted new laws that could increase our tax obligations in countries in which we do business or cause us to change the way we operate our business. These recent changes and proposals could negatively impact our taxation, especially as we expand our relationships and operations internationally.

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***If we or any of our subsidiaries are treated as a “controlled foreign corporation” for U.S. federal income tax purposes, certain U.S. Holders may be subject to adverse U.S. federal income tax consequences.***

If a “United States person” (as defined in Section 7701(a)(30) of the Code) is treated as owning (directly, indirectly, or constructively) at least 10% of the total combined voting power of all classes of our shares entitled to vote or at least 10% of the total value of shares of all classes of our shares, such person may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” (“CFC”) within the meaning of Section 957(a) of the Code in us (if any), which may subject such person to adverse U.S. federal income tax consequences. Specifically, a United States shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of such CFC’s “Subpart F income,” “global intangible low-taxed income,” and investments in U.S. property, whether or not we make any distributions of profits or income of such CFC to such United States shareholder. If a U.S. Holder is treated as a United States shareholder of a CFC, failure to comply with applicable reporting obligations may subject such holder to significant monetary penalties and may extend the statute of limitations with respect to such holder’s U.S. federal income tax return for the taxable year for which reporting was due. Additionally, an individual United States shareholder of a CFC generally would be denied certain tax deductions or foreign tax credits in respect of its income that may otherwise be allowable to a United States shareholder that is a U.S. corporation.

In light of our structure, certain of our non-U.S. subsidiaries may be CFCs. We cannot provide any assurances that we will assist U.S. Holders in determining whether we or any of our non-U.S. subsidiaries is treated as a CFC or whether any U.S. Holder is treated as a United States shareholder with respect to any such CFC, nor do we expect to furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. U.S. Holders should consult their tax advisors regarding the potential application of the CFC rules to an investment in ordinary shares.

***If we are or become a “passive foreign investment company” for U.S. federal income tax purposes, U.S. Holders may be subject to adverse U.S. federal income tax consequences.***

Based on our income, assets, and operations and our subsidiaries, we do not believe we were a PFIC in the taxable year ended March 31, 2025, although there can be no assurance that the IRS or a court will not challenge our position in this regard. The determination of whether we are a PFIC is made on an annual basis and will depend on the composition of our income and assets of and our subsidiaries, and the value of our assets of and our subsidiaries, from time to time. Specifically, for any taxable year, a non-U.S. corporation will be classified as a PFIC for U.S. federal income tax purposes if either: (1) 75% or more of its gross income in such taxable year is passive income, or (2) 50% or more of the value of its assets (generally based on an average of the quarterly values of the assets) during such taxable year is attributable to assets that produce or are held for the production of passive income. The calculation of the value of our assets of and our subsidiaries will be based, in part, on the quarterly market value of ordinary shares, which is subject to change and may be volatile.

The determination of whether we are a PFIC also will depend, in part, on how, and how quickly, we use our liquid assets and cash. If we were to retain significant amounts of liquid assets, including cash, the risk of us being classified as a PFIC may substantially increase. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for any future taxable year, and no opinion of counsel has or will be provided regarding the classification of us as a PFIC. If we were classified as a PFIC for any taxable year during which a U.S. Holder held ordinary shares, we generally would continue to be treated as a PFIC for all succeeding taxable years during which such U.S. Holder held ordinary shares.

If we were classified as a PFIC, such characterization could result in adverse U.S. federal income tax consequences to U.S. Holders, including increased tax liabilities under U.S. federal income tax laws and regulations and burdensome reporting requirements. We cannot assure any U.S. Holder that we will not be a PFIC for the current taxable year or any future taxable year. U.S. Holders should consult their tax advisors regarding the circumstances that may cause us to be classified as a PFIC and the consequences if we are classified as a PFIC.

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***We may not be able to satisfy the Nasdaq listing requirements or obtain or maintain a listing of the ordinary shares on Nasdaq.***

As the ordinary shares are listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate the Nasdaq listing requirements, or if we fail to meet any of the Nasdaq listing standards, the ordinary shares may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. The delisting of the ordinary shares from Nasdaq could significantly impair our ability to raise capital and the value of your investment.

***Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares for return on your investment.***

We currently intend to retain most, if not all, of our available funds and any future earnings after this offering to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in the ordinary shares as a source for any future dividend income.

Our board of directors has complete discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Islands law, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in us being unable to pay our debts as they fall due in the ordinary course of business. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in the ordinary shares will likely depend entirely upon any future price appreciation of the ordinary shares. There is no guarantee that the ordinary shares will appreciate in value in the future or even maintain the price at which you purchased the ordinary shares. You may not realize a return on your investment in the ordinary shares and you may even lose your entire investment in the ordinary shares.

***Our controlling shareholder will have considerable influence over us and certain of our corporate matters.***

Ms. Huaqin Xue controls 51.01% of the total voting power of all issued and outstanding ordinary shares. Ms. Xue currently exercises voting and dispositive control over the ordinary shares registered in the name of Crystal Peak Investment Inc., a limited liability company incorporated under the laws of the British Virgin Islands. On July 8, 2025, we entered into a Share and Warrant Purchase Agreement with Crystal Peak Investment Inc., a limited liability company incorporated under the laws of the British Virgin Islands (“Crystal Peak”), pursuant to which we sold 16,987,542 ordinary shares and 16,987,542 detachable warrants in a private placement transaction for a total consideration of US$15 million. Subsequently, on July 9, 2025, these warrants were fully exercised on a cashless basis, resulting in the issuance of 4,033,790 ordinary shares, which were formally recorded and made effective on July 11, 2025. Pursuant to the Share and Warrant Purchase Agreement, Ms. Xue is restricted from directly or indirectly causing any changes in the composition of the Board or senior management, including the election and appointment of directors and officers, so long as she holds any of our equity securities. However, as the beneficial owner of a majority of our outstanding ordinary shares, Ms. Xue has considerable influence to affect our corporate actions that require shareholder approval under Cayman Islands law, such as approving any statutory merger pursuant to the Cayman Islands Companies Act and amending our memorandum and articles of association, or other significant corporate transactions. This control will limit your ability to influence corporate matters and may prevent transactions that would be beneficial to you, including discouraging others from pursuing any potential merger, takeover or other change of control transactions, which could have the effect of depriving the holders of the ordinary shares of the opportunity to sell their shares at a premium over the prevailing market price. As a result, investors may be subject to the risk that Ms. Xue’s interests may not always align with the interest of our other shareholders.

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***Techniques employed by short sellers may drive down the market price of the ordinary shares.***

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 the ordinary shares 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 itself. 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 ordinary shares could be greatly reduced or rendered worthless.

***Sales of the ordinary shares, or the perception of such sales, by us or the selling securityholders in the public market or otherwise could cause the market price for the ordinary shares to decline.***

We filed a registration statement on Form F-1 (File No.: 333-271221), effective on June 5, 2023, to facilitate the resale of our ordinary shares by the selling security holders identified therein. The sale of the ordinary shares in the public market or otherwise, including sales by us or the selling security holders, or the perception that such sales could occur, could increase the volatility of the market price of the ordinary shares or result in a significant decline in the public trading price of the ordinary shares. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of the ordinary shares may cause the market price of our securities to drop significantly.

In addition, we have granted shares options, restricted share units or other types of share-based awards to employees, directors and consultants pursuant to our share incentive plans, and may continue to make such grants in the future. To the extent that any of these awards are vested and/or exercised, and any of such shares are sold in the market, it could have an adverse effect on the market price of the ordinary shares.

**ITEM 4. INFORMATION ON THE COMPANY**

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| **A.** | **History and Development of the Company** |

We were incorporated under the laws of Cayman Islands as an exempted company with limited liability in November 2020. We own seven companies and their subsidiaries that were incorporated in the United States of America, Singapore, Hong Kong, the Philippines and the People’s Republic of China.

On September 29, 2022, we entered into the Business Combination Agreement with, among others, SPAC. As a result of and upon consummation of the Business Combination, the holders of shares and/or warrants of SPAC has become the holders of our shares and/or warrants. The Business Combination was consummated on March 16, 2023. On March 17, 2023, the ordinary shares and Warrants commenced trading on Nasdaq, under the symbols “YS” and “YSBPW,” respectively. In connection with the change of our legal name to LakeShore Biopharma Co., Ltd, the ordinary shares and Warrants began trading under the symbols “LSB” and “LSBPW,” respectively, effective from May 28, 2024.

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On September 27, 2024, our shareholders approved the resolution to consolidate every ten shares, par value of US$0.00002 each (whether issued or unissued), into one ordinary share, par value of US$0.0002 each (the “Share Consolidation”), such that following the Share Consolidation, the authorized share capital of the Company shall be changed from US$50,000 divided into 2,500,000,000 ordinary shares of a par value of US$0.00002 each to US$50,000 divided into 250,000,000 ordinary shares of a par value of US$0.0002 each. The Share Consolidation has been effective since October 1, 2024.

The mailing address of our principal executive office is Building No. 2, 38 Yongda Road Daxing Biomedical Industry Park, Daxing District, Beijing, PRC, and our phone number is +86-10-89202086. Our corporate website address is www.lakeshorebio.com. Our website and the information contained on, or that can be accessed through, the website is not deemed to be incorporated by reference in, and is not considered part of, this Annual Report.

We are subject to the informational reporting requirements of the Exchange Act. We file reports and other information with the SEC under the Exchange Act. Our SEC filings are available over the Internet at the SEC’s website at www.sec.gov. Our corporate website address is www.lakeshorebio.com. Our website and the information contained on, or that can be accessed through, the website is not deemed to be incorporated by reference in, and is not considered part of, this Annual Report.

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| **B.** | **Business Overview** |

We are a global biopharmaceutical company dedicated to discovering, developing, manufacturing and commercializing new generations of vaccines and therapeutic biologics for infectious diseases and cancer.

We commercialize vaccines with significant revenue and growth potential. We take pride in our marketed vaccine product, YSJATM rabies vaccine, which was the first aluminum-free lyophilized rabies vaccine launched in China. YSJATM rabies vaccine improves the suitability of human rabies vaccine to rabies in China and causes less pain, injection site discomfort and fever to patients compared to certain other rabies vaccines in China. In addition, YSJATM rabies vaccine is suitable for mass production and commercialization with long shelf life and low risk of contamination. As of March 31, 2025, approximately 110 million doses of YSJATM rabies vaccine have been administered for post-exposure protection against rabies. With our track record of commercialization, YSJATM rabies vaccine has achieved high production scalability and wide market recognition. Since we commenced the sales of YSJATM rabies vaccine in October 2020 and to March 31, 2025, we sold more than 35.3 million doses of YSJATM rabies vaccines to 1,911 county-level CDCs in China, covering 67.7% of all county-level CDCs in China.

In addition to the commercialized YSJATM rabies vaccine, we also have a pipeline of vaccine candidates powered by our proprietary PIKA immunomodulating technology platform. Our proprietary PIKA immunomodulating technology platform is core to the discovery and development of innovative biologics and will continue to be instrumental to our success. As of the date of this report, we have a portfolio of seven innovative product candidates: (1) five product candidates under various clinical development stages, including PIKA rabies vaccine, PIKA YS-ON-001, PIKA YS-HBV-001, PIKA YS-HBV-002 and simplified four-dose regimen for YSJA™, and (2) two preclinical stage product candidates, targeting influenza, and cancer with enormous medical demand. In addition, we are working on the second generation of PIKA adjuvant at the discovery stage. We have been granted about 46 patents across more than 14 countries and regions relating to our PIKA immunomodulating technology and prophylactic and therapeutic product innovations. We believe that our PIKA immunomodulating technology platform has the potential to nurture a wide variety of innovative vaccines and therapeutic biologics.

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In October 2024, we have been granted approval for a Phase III clinical trial by the NMPA to explore the immunogenicity and safety of a simplified four-dose regimen for our YSJATM rabies vaccine. The two four-dose immunization regimens which will be explored are the Zagreb Regimen (2-1-1), which involves two shots in the first session and one shot each across two subsequent sessions; and the Modified Essen Regimen (1-1-1-1), which involves four sessions of a single shot each. Compared to the conventional five-dose, Essen regimen (1-1-1-1-1), this simplified immunization schedule has the potential to provide patients with more immunization options, reduce physician workload, minimize hospital visits, improve patient adherence to vaccination and also reduce the financial burden on patients under comparable immunogenicity, boosting the vaccine’s utility and aiding in the prevention of rabies deaths. We have commenced this clinical trial in December 2024 and we expect to finish the interim analysis in the fourth quarter of 2025 and obtain the market approval in the fourth quarter of 2026.

We have been manufacturing YSJATM rabies vaccine and clinical trial samples of clinical candidates in our current GMP-compliant facilities. We have also obtained patents on our manufacturing techniques and devices. Our current manufacturing facilities have an annual production capacity of approximately 15 million doses of YSJATM rabies vaccine. We have a comprehensive and effective commercialization infrastructure, underpinned by our experienced in-house commercialization team and professional service providers. As of March 31, 2025, our in-house commercialization team managed our sales and marketing activities across 307 cities in China. We believe that our product candidates, if approved and launched, will benefit from the operating leverage enabled by our accumulated commercialization experience and scalable commercialization infrastructure to achieve market success.

**Our Marketed Product and Product Candidates**

We adopted a self-developed approach with respect to our PIKA-adjuvanted product pipeline. Our PIKA adjuvant is based on a novel mechanism of action for adjuvants supported by our PIKA immunomodulating technology platform, through which we are developing prophylactic and therapeutic biologics. We made significant in-house advancement of PIKA immunomodulating technology, such as in researching our mechanism of action, developing multiple clinical applications, establishing PIKA-related manufacturing capabilities and enhancing our IP protection. We further combined PIKA adjuvant with well-established vaccine mechanism of action, such as those for rabies and HBV, to develop a pipeline of innovative vaccines targeting specific viral infections. In addition to leveraging our PIKA immunomodulating technology platform, our marketed product, YSJATM rabies vaccine, is a validated, conventional rabies vaccine product based on a well-established mechanism of action of rabies vaccine which provides important market presence and cash flow to support our ongoing business expansion.

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***Overview***

Our portfolio consists of eight biologics, including one marketed product, five clinical-stage candidates and two preclinical candidates. In addition, we are working on a series of therapeutic targets and products at the discovery stage. The following table summarizes the development status of our portfolio of marketed product and product candidates.

A screenshot of a computer screen

AI-generated content may be incorrect.

Our candidates are subject to approval by the relevant authorities, such as the NMPA of China, the HSA of Singapore and/or other equivalent authorities before commercialization in such jurisdictions.

***Vaccine mechanism of action***

Vaccine is a biological product to safely induce an immune response that confers protection against infection and/or disease on subsequent exposure to a pathogen. To achieve such goal, vaccines are mostly designed to address natural defense mechanisms and activate the immune system in a manner similar to natural infections.

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The human immune system comprises two major components: the innate and the adaptive immune system. Innate and adaptive immunity work sequentially to identify invading pathogens and initiate the most effective defense response. The interaction of innate and adaptive immunity is crucial to generate and maintain a protective immune response. Specialized antigen-presenting cells (APCs) are especially important to bridge the two components of the immune system.

The innate immune system represents the first line of host defense against pathogens which includes the body’s physical barriers (e.g., skin, mucosal membranes, and enzymes), molecules (e.g., complement) and cells (e.g., macrophages, dendritic cells, neutrophils, monocytes, and natural killer cells). The innate immune system senses the invasion of pathogen via pattern recognition receptors (PRRs) expressed on innate immune cells. Toll-like receptors (TLRs), a class of PRRs, recognize pathogen-associated molecular patterns (PAMPs) that are shared by several pathogens. For instance, TLR3 recognizes viral double-stranded RNA. The binding of TLRs triggers secretion of chemical messengers, such as cytokines and chemokines, from infected cells and/or innate immune cells to attract other resident and circulating innate cells to the site of infection, and leads to the development of adaptive immune responses.

The adaptive immune system is the second line of immunological defense. Unlike the innate immune defense, which is fast reacting but lacks specificity, adaptive immune responses are antigen specific. Moreover, memory cells are generated in the course of adaptive immune response, which provide a faster and stronger immune response when the body encounters the same pathogen in the future. The adaptive immune responses are mediated by APCs that capture and digest the antigen that are complexed with major histocompatibility complexes (MHCs) and presented to lymphocytes. There are two subsets of lymphocytes, namely B cells and T cells. Activated B cells can produce and secrete antigen specific antibodies that can facilitate phagocytosis or complement-mediated killing of pathogens or neutralize toxins by binding to their appropriate antigens. There are two major subsets of T cells, CD4+ T cells with regulatory functions and CD8+ T cells with effector functions. In most cases CD4+ cells will help other immune cells perform their task and are referred to as helper T cells (Th). T helper 2 (Th2) cells secrete mainly interferon-gamma (IFNI’), a cytokine known to limit pathogen survival and promote the differentiation of CD8+ cells. Th2 cells produce various cytokines (e.g., interleukins (IL) including IL-4, IL-5 and IL-13) that preferentially activate innate immune cells (e.g., eosinophils and mast cells) and facilitate especially the immune response to extracellular pathogens. Another subset, termed follicular T helper cell (Tfh) is characterized by the secretion of IL-21, a cytokine thought to favor the secretion of antibodies by antigen-specific B cells. Finally, regulatory CD4+ T cells (Treg cells) inhibit immune or inflammatory responses by blocking the activity of effector T cells, helper T cells, and APCs.

CD8+ T cells can destroy cells infected by intracellular pathogens such as viruses by secretion of cytotoxic factors. In addition, CD8+ T cells can inhibit viral replication without destroying the infected cells by producing cytokines (interferon) to interfere with pathogen replication. CD8+ cytotoxic cells also can eliminate cells exhibiting abnormal host peptides, such as those presented by tumor cells, and therefore play an important role in the immune control of aberrant cell growth.

***YSJATM Rabies Vaccine—Our marketed product***

YSJATM rabies vaccine is an aluminum-free, inactivated Vero cell based vaccine, which is the first aluminum-free lyophilized rabies vaccine developed in China. As of March 31. 2-25, approximately 110 million doses have been administered to patients for post-exposure protection against rabies. YSJATM rabies vaccine improves the suitability of human rabies vaccine to rabies in China and causes less pain, injection site discomfort and fever to patients compared with certain rabies vaccines in China. Our current manufacturing facilities in Shenyang, China received the GMP certificate in July 2019, pursuant to which we started the production of YSJATM rabies vaccine in February 2020 and its sales in October 2020. Since October 2020 and up to March 31, 2025, we sold more than 35.3 million doses of YSJATM rabies vaccines to 1,911 county-level CDCs in China.

In October 2024, we have been granted approval for a Phase III clinical trial by the NMPA to explore the immunogenicity and safety of a simplified four-dose regimen for our YSJATM rabies vaccine. This simplified immunization schedule has the potential to provide patients with more immunization options, reduce physician workload, minimize hospital visits, improve patient adherence to vaccination and also reduce the financial burden on patients under comparable immunogenicity, boosting the vaccine’s utility and aiding in the prevention of rabies deaths. We have commenced this clinical trial in December 2024, which will evaluate the immunogenicity and safety of the YSJATM rabies vaccine across two distinct four-dose immunization schedules to determine their immunogenicity and safety compared to the existing Essen regimen (1-1-1-1-1). It will be a single center, randomized, double-blind, controlled study. The two four-dose immunization regimens which will be explored are the Zagreb Regimen (2-1-1), which involves two shots in the first session and one shot each across two subsequent sessions; and the Modified Essen Regimen (1-1-1-1), which involves four sessions of a single shot each. Compared to the conventional five-dose, Essen regimen (1-1-1-1-1), both options offer greater flexibility for medical professionals and patients and stand to improve the existing standard of rabies care. We expect to finish the interim analysis of this clinical trial in the fourth quarter of 2025 and obtain the market approval in the fourth quarter of 2026.

*Mechanism of action*

Rabies neutralizing antibodies are widely accepted to correlate with the protection against rabies. A minimum level of 0.5 IU/mL is used by the WHO as a correlate of protection. This level of rabies virus neutralizing antibodies should be achieved by day 14 of post-exposure immunization.

*Market opportunity and competition*

Human rabies is a viral disease that causes acute encephalitis with almost 100% mortality rate if post-exposure prophylaxis (PEP) is not administered timely prior to the onset of symptoms. In most developing countries, immediate PEP is adopted to control the incidences and deaths from rabies.

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Human rabies occurs in more than 150 countries and territories worldwide and is a significant public health concern in developing countries, especially in many Asian and African countries, with approximately 35,000 rabies-caused deaths occurring each year in Asia, according to the WHO. Thanks to human rabies vaccine, the number of new incidences of rabies infection in China decreased from 801 in 2015 to 170 in 2024, out of which the number of deaths was 744 and 143 in 2015 and 2024, respectively, and human rabies vaccine is expected to continue to play a critical role in suppressing rabies in China in the future.

Due to various factors such as the change in the number of market players, adjustment in production volume and the impact of a scandal involving the then second largest rabies vaccine manufacturer in July 2018, the market value of China’s rabies vaccine fluctuated during 2015 and 2019, with an overall decline at a negative CAGR of 4.7%. China’s human rabies vaccine market production value is expected to increase from RMB9.4 billion in 2021 to RMB22.1 billion in 2025, a CAGR of 23.8%, and is expected to increase to RMB33.3 billion in 2030, representing a CAGR of 8.5%.

*Advantages*

YSJATM rabies vaccine uses fixed CTN-1 strain to produce vaccine in Vero cells, which demonstrates advantages such as:

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|  | ● | *Improved suitability for rabies in China*. The sequence analysis has shown that the homology between CTN-1 strain and most wild Chinese rabies isolates was between 81.5% to 93.4%, higher than PM-1 strain used in other licensed vaccines, which has made CTN-1 strain more suitable for rabies in China. Approximately 98 million doses of YSJATM rabies vaccine have been administered in China. |

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|  | ● | *Higher immunogenicity*. A head-to-head study conducted by an independent clinical research group in 2007 demonstrated that CTN-1 strain-derived rabies vaccine produced higher immunogenicity than rabies vaccine using other virus strains. |

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|  | ● | *Better safety profile*. According to a head-to-head study, the administration of YSJATM rabies vaccine causes less pain and injection site discomfort to patients. YSJATM rabies vaccine is also associated with a lower rate of fever compared with certain other rabies vaccines in China. |

Four head-to-head clinical studies were conducted by certain CDC centers in China to evaluate the safety and adverse reactions between the YSJATM rabies vaccine and other rabies vaccines marketed by other producers. Such trials included both children under 10 years old and adult patients. The head-to-head study among adult patients also evaluated the immune responses of various human use rabies vaccines marketed in China.

The material details of such four head-to-head clinical studies are set out below:

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|  | (1) | A head-to-head clinical study conducted by Guangxi CDC center in China to evaluate adverse reactions of YSJATM rabies vaccine and another leading product in China among children under 10 years old. |

The trial enrolled 1025 children under 10 years old including 477 subjects and 548 subjects receiving YSJATM rabies vaccine and the comparison vaccine, respectively. The results showed that the rate of fever among patients receiving the comparison vaccine was 48.4% (265/548), higher than the rate of fever to patients of YSJATM rabies vaccine 18.4% (88/477) (P<0.05). In the comparison group, fever was most common in children under 3 years old. The older the age, the lower the probability of fever. The study recommended to use YSJATM rabies vaccine for children under 10 years old, especially under 3 years old to reduce the incidents of adverse reactions.

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|  | (2) | A head-to-head clinical study conducted by Guizhou CDC center in China to evaluate adverse reactions and immune response of YSJATM rabies vaccine and another leading product among adult patients. |

The 100 subjects enrolled in the study were randomized into two groups (50 in study group receiving YSJATM rabies vaccine and 50 in control group receiving the other leading products). The result showed there were three cases of adverse reactions reported in the YSJATM rabies vaccine group, lower than the total number of adverse reactions in the control group of 10 cases (20%). Comparing the antibody seroconversion rate between two groups, the total number of seroconversion cases in the study group was 49 (98%), and the total number of seroconversion cases in the control group was 40 (80%) (P<0.05). The study concluded that the adverse reaction rate of YSJATM rabies vaccine was lower and the seroconversion rate was higher comparing to those of the other leading product.

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|  | (3) | A head-to-head study conducted by Qiannan CDC center in Guizhou, China to evaluate adverse reactions of YSJATM rabies vaccine and another leading product in China. |

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The trial enrolled 206 post-exposure patients including 102 subjects and 104 subjects receiving YSJATM rabies vaccine and the comparison vaccine, respectively to observe the incidence of adverse reaction after 72 hours of the injection. The results showed that the adverse reactions rate receiving the comparison vaccine was 24.03%, higher than the adverse reactions rate receiving YSJATM rabies vaccine 8.82%. The difference was statistically significant (P<0.01). The study recommends using YSJATM rabies vaccine as the first choice due to its lower rate of adverse reactions.

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|  | (4) | A head-to-head clinical study conducted by Yiwu CDC center in Zhejiang, China to evaluate adverse reactions of YSJATM rabies vaccine with an imported lyophilized rabies vaccine and another domestic liquid rabies vaccine. |

The trial enrolled 300 post-exposure patients who were randomized into three groups (100 subjects receiving YSJATM rabies vaccine, 100 subjects receiving an imported lyophilized rabies vaccine and 100 subjects receiving a domestic liquid rabies vaccine) to observe the adverse reaction incidences and the immune responses after 14 and 42 days of the first injection, respectively. The results showed that the local adverse reactions rates receiving the YSJATM rabies vaccine, imported lyophilized rabies vaccine and domestic liquid rabies vaccine were 3.6%, 3.2% and 28.6% respectively and the systemic adverse reactions rates for the 3 groups were 1.2%, 0.8% and 4.4% respectively. Comparing the seroconversion rate measured by neutralizing antibody titers among 3 groups, the seroconversion rates receiving the YSJATM rabies vaccine, imported lyophilized rabies vaccine and domestic liquid rabies vaccine were 96%, 98% and 82% after 14 days of the first injection; 98.98%, 98.99% and 93.68% after 42 days of the first injection. The study concluded that, compared to the liquid rabies vaccine, the lyophilized rabies vaccine showed statistical significance with lower adverse reaction rate, higher seroconversion rate and longer terms of validity. There was no statistical significance between YSJATM rabies vaccine and the imported lyophilized rabies vaccine in terms of the adverse reaction rate and seroconversion rate but YSJATM rabies vaccine was more affordable with a lower price for most post-exposure patients to meet their needs domestically.

Moreover, the adoption of purified Vero cell technology in YSJATM rabies vaccine offers several advantages in terms of mass production, such as:

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|  | ● | *High production scalability*. Purified Vero cell technology provides high scalability suitable for mass production, which also achieves high product quality and low risk of exogenous contamination, based on the Technical Guidelines for Human Rabies Prevention and Control (2016) issued by the national CDC in China. |

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|  | ● | *Established product profile*. Approximately 110 million doses of YSJATM rabies vaccine have been administered in China, consistent with less side effects of rabies vaccines under Vero cell technology claimed by Technical Guidelines for Human Rabies Prevention and Control (2016). |

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|  | ● | *Enhanced convenience and stability*. YSJATM rabies vaccine is in freeze-dried (as opposed to a liquid) form, and is easier to store and transport as well as less susceptible to changes in temperature, reducing potential product spoilage. |

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|  | ● | *Reliable purity.* We successfully developed a series of proprietary and patented purification technologies to effectively remove residual DNA and protein impurities during the manufacturing process, which helps ensure the quality and purity of our vaccine products for human use. |

*Commercialization and marketing plan*

We received the GMP certificate for our manufacturing facilities in Shenyang, China in July 2019, pursuant to which we started the production of YSJATM rabies vaccine in February 2020 and the sales in October 2020. From October 2020 to March 31, 2025, we sold more than 35.3 million doses to 1,911 county-level CDC customers in China. In addition, we developed more advanced bioreactor engineering process to improve our production throughput, efficiency and quality control. Under our business expansion strategy, we continue to increase the number of our in-house commercialization team and increase the number of external service providers to reach our target coverage of county-level CDC customer accounts of approximately 2,272 in China.

To expand our international market operation, we also seek potential partnership and licensing with leading pharmaceutical companies to commercialize YSJATM rabies vaccine in certain international market. We intend to expand our commercialization efforts into countries throughout Southeast Asia.

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***Our clinical stage product candidates***

Leveraging our proprietary PIKA immunomodulating technology platform, we developed a pipeline of product candidates targeting viral infections and cancer. Our PIKA molecule is a class of double strand RNA (dsRNA) molecules of well-defined, specific ribonucleic acid units and molecular weight distribution synthesized with our proprietary technology. Endosomal dsRNA can be recognized by TLR3 while cytosolic dsRNA can be sensed by the retinoic acid-inducible gene (RIG) I-like receptor (RLR) family which include RIG-I and melanoma differentiation-associated protein 5 (MDA5). The immuno-potentiating effects of PIKA include: (1) promoting the activation and maturation of dendritic cells, (2) up-regulating the co-stimulatory molecules, such as CD80, CD86 and HLA-DR on dendritic cell, (3) activating and promoting the maturation of dendritic cells, (4) enabling the dendritic cells to act as potent antigen presenting cells for effective activation of naive B and T lymphocytes which in turn lead to a more robust specific immune response, (5) inducing the activation and proliferation of both B cells and NK cells, (6) triggering the TLR3 pathway which induces IL-2 and type I IFNs production, (7) improving MHC category II expression and cross-presentation of antigen, and (8) promoting Th1 (cellular) based immunity through our induction of IL-2 and type I IFNs.

For more details, see “—Research and Development—PIKA Immunomodulating Technology Platform.” The following figure sets forth the signaling pathway and function of PIKA.

Figure 1. Signaling Pathway and Function of PIKA

A diagram of a cell division

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*PIKA Rabies Vaccine*

PIKA rabies vaccine is a lyophilized human-use rabies vaccine composed of cell culture-derived rabies antigen mixed with PIKA adjuvant which acts as a TLR3 agonist. This vaccine candidate is based upon our deep foundation in YSJATM rabies vaccine, coupled with our proprietary PIKA adjuvant and advanced manufacturing techniques. Leveraging our proprietary PIKA immunomodulatory technology platform, PIKA rabies vaccine is designed to induce accelerated and strong cellular immunity and stimulate the body to rapidly produce higher humoral immune response. Its accelerated onset of immune response allows a three-visit one-week regimen superior to the currently available vaccine with a five-visit one-month or three-visit three-week regimen, which shortens the treatment period by two to three weeks. It also significantly accelerates generation of immunization from 28 days to 7 days, which has the potential of becoming the first accelerated one-week regimen upon the completion of the new drug application (“NDA”). This vaccine candidate was designated by a WHO expert committee background paper publication as an innovative rabies vaccine.

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We received approval of Phase III clinical trials of PIKA Rabies vaccine from the regulatory authorities in the Philippines and Pakistan. The Phase III clinical trial is a randomized, comparator-controlled, double-blind, multi-country and multi-center study that started in the second half of 2023 and is currently being conducted in Pakistan and the Philippines. We completed the subject enrollment in its Phase III clinical trial in Pakistan and the Philippines, which included 4,500 subjects, targets to assess the safety, immunogenicity, and lot-to-lot consistency of the PIKA rabies vaccine in healthy adults using a 7-day vaccine schedule, versus a globally marketed comparator following the standard 28-day regimen. The results of this Phase III clinical trial have met the primary endpoints of the trial, demonstrating its potential to achieve accelerated protection and meet the WHO’s goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens. In China, we have completed Phase I study of PIKA rabies vaccine, and the preliminary results confirm the dose, regimen and safety observed from the Singapore trials. We are currently discussing with the NMPA to launch more advanced trials in China. Based on the Phase III results from the clinical trials in Philippines and Pakistan, we initiated Biologics License Application (“BLA”) submission to the Drug Regulatory Authority of Pakistan for the conditional approval of our PIKA rabies vaccine for post-exposure prophylaxis in November 2024. We decided to put the study on hold as we are currently evaluating the commercial potential and regulatory requirements for the Southeast Asia region.

*Mechanism of action*

PIKA rabies vaccine is composed of cell culture-derived rabies antigen mixed with PIKA adjuvant that is acting as a TLR3 agonist. As a result, PIKA rabies vaccine has a distinct role in promoting cellular and humoral immunity and thus has the dual prophylactic and post-exposure therapeutic characteristics. In particular, the high level of innate immune response and balanced Th1/Th2 immune response induced by PIKA rabies vaccine play a crucial role in the protection of rabies virus. PIKA rabies vaccine can quickly induce the production of a variety of chemokines and cytokines, and improve the proliferation and activation of immune cells, which plays a very important early protective role in patients after exposure. For a description of mechanism of action for rabies vaccines, see “—YSJATM Rabies Vaccine—Our marketed product—Mechanism of action.”

*Market opportunity and competition*

PIKA rabies vaccine is under clinical trial indicated for both pre- and post-exposure rabies prophylaxis and was designated by a WHO expert committee document as innovative rabies vaccine in 2017. This product candidate was also granted ODD by the U.S. FDA for prevention of rabies infection including post-exposure prophylaxis for against rabies. PIKA rabies vaccine is designed as a premium product that targets the high-end rabies vaccine market and differentiates from existing conventional rabies vaccines. We expect it to become the next generation of rabies vaccine and capture significant opportunity in China and other emerging markets, or even replace conventional rabies vaccines, given its accelerated one-week regimen, and enhanced protection level, especially in light of the insufficient supply and usage of rabies immunoglobulin in less developed countries. As our PIKA rabies vaccine has entered Phase III clinical development, we are also exploring potential partnerships to jointly commercialize this promising product in many countries.

*Advantages*

According to the WHO guidance, the most commonly used biologics to treat rabies are PEP regimen that consists of rabies vaccine with the combination of rabies immunoglobulin. However, they have the following limitations:

|  |  |  |
| --- | --- | --- |
|  | ● | *PEP rabies vaccine regimens.* The two most common PEP rabies vaccination regimens are the Essen (five injections administered on days 0, 3, 7, 14, and 28) and the Zagreb schedule (two injections administered on day 0 and one injection on days 7 and 21). However, the administration of PEP must be as early as possible to give the optimal chance of protection against developing clinical disease. Deviation from the recommended PEP protocol could also result in clinical rabies. In addition, fatalities are common even after the administration of appropriate PEP, particularly when rabies immunoglobulin has not been either administered or appropriately administered. Severe bites to highly innervated areas, such as face, neck or hand, significantly shorten the incubation period, which causes insufficient time for the development of a protective immune response. Suboptimal response of current vaccine has been reported in populations with compromised immunity, such as HIV/AIDS-infected patients, and with immature immunity, such as children. The WHO has recognized the limitations of current rabies PEP practice and is tasked to reduce the duration of course and number of doses administered under the current PEP regimen. Animal challenge experiments have also *indicated* that rabies vaccine alone does not offer guaranteed protection because the injection of the vaccine usually takes 10-12 days to produce sufficient antibodies, which lags behind the time that the virus proliferates and invades the nerve tissue in the local muscle cells. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Rabies immunoglobulin*. The treatment currently recommended by the WHO requires the administration of rabies immunoglobulin, which is a type of rabies neutralizing antibodies derived from human blood, together with rabies vaccines. The injected antibodies act to neutralize the rabies virus before the human immune system produces its own antibodies. However, immunoglobulin is often expensive and limited in supply in developing countries. In China, the adoption rate of rabies immunoglobulin is relatively low. According to the Technical Guidelines for Human Rabies Prevention and Control (2016), it is estimated that over 90% of post- exposure patients at clinics in some provinces with higher incidence of rabies in China can be classified as category II and III which require the PEP regimen of rabies vaccine with the combination of rabies immunoglobulin, of which approximately 40% falls under category III, the most severe type in terms of wounds. However, the local injection of rabies immunoglobulin is still a painful and costly procedure, and it is estimated that only 15% of category III patients received rabies immunoglobulin injection, according to the same source. |

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The excellent immunogenicity and lack of serious adverse events under the accelerated PIKA rabies vaccine program has been recognized by the WHO. The WHO highlighted PIKA rabies vaccine in their 2017 background paper on rabies. A successful PIKA rabies vaccine will further the WHO’s agenda to reduce the course of rabies vaccine. PIKA rabies vaccine has the following advantages over the existing rabies vaccine.

|  |  |  |
| --- | --- | --- |
|  | ● | *Dual prophylactic and therapeutic characters.* PIKA rabies vaccine has a distinct role in promoting cellular and humoral immunity in the type of immune response and thus has the dual character of both prophylactic and therapeutic vaccines. In particular, balanced CD4 and CD8 cellular immune responses play a key role in post-exposure immune protection. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Earlier and higher neutralizing antibody production.* The improved 2-2-1 immunization regimen provides accelerated and strong specific immune response for early protection and improves the patient compliance of immunization. The clinical studies to date have shown that PIKA rabies vaccine can be used under an accelerated regimen, achieving protective level of neutralizing antibodies as early as seven days post vaccination, eliciting more robust immunogenic response compared to that of the control arm vaccine, which is a widely used commercially available vaccine. PIKA rabies vaccine has also showed good reactogenicity and tolerability, comparable to that of the commercially available vaccine. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Induction of strong cellular immunity.* PIKA rabies vaccine can activate cellular immunity, including specific and nonspecific cellular immunity. Clinical study has shown that PIKA rabies vaccine is capable of inducing more potent T cell response than currently available rabies vaccines, which is beneficial for protection after exposure. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Potential to enhance protection without immunoglobulin.* PIKA rabies vaccine used under accelerated regimen may achieve protective level of neutralizing antibody as early as seven days post vaccination, which minimize the risk for patients who fail to adopt rabies immunoglobulin. Given the insufficient supply and low adoption rate of immunoglobulin in China and other developing countries, PIKA rabies vaccine has the potential to enhance the protection level than that of commercially available rabies vaccine. |

*Summary of preclinical and clinical studies*

To capture the underserved market demand for new generations of rabies vaccines in the emerging markets, we developed a global clinical development plan comprising, generally in chronological order, the following clinical trials:

(1) a Phase I trial among 37 healthy volunteer subjects in Singapore, completed in February 2016;

(2) a Phase II trial among 126 healthy volunteer subjects in Singapore, completed in July 2016;

(3) a Phase I trial among 96 healthy volunteer subjects in China to confirm the dose regimen and safety observed in Singapore clinical trials, completed in 2021;

(4) a multi-country, multi-center Phase III registration trial among approximately 4,500 healthy subjects using a post exposure prophylaxis schedule was conducted in Pakistan and the Philippines. The last visit was completed in November 2024; and serum samples are currently undergoing testing

(5) more advanced trials to be conducted in China upon the consultation and approval by the NMPA in China.

(6) We received the approval of the Phase III clinical trials of PIKA Rabies vaccine from the regulatory authorities in the Philippines and Pakistan. The Phase III Trial is a randomized, comparator-controlled, double-blind, multi-country and multi-center study that started in the second half of 2023 and is currently being conducted in Pakistan and the Philippines. We completed the subject enrollment in its Phase III clinical trial in Pakistan and the Philippines, which included 4,500 subjects, targets to assess the safety, immunogenicity, and lot-to-lot consistency of the PIKA rabies vaccine in healthy adults using a 7-day vaccine schedule, versus a globally marketed comparator following the standard 28-day regimen. The results of this Phase III clinical trial have met the primary endpoints of the trial, demonstrating its potential to achieve accelerated protection and meet the WHO’s goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens. In China, PIKA rabies vaccine completed Phase I study of PIKA rabies vaccine to confirm the dose, regimen and safety observed from the Singapore trials. We plan to conduct more advanced clinical trials in China upon the consultation and approval by the NMPA in China.

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Based on the results of Phase III clinical trials in Philippines and Pakistan, we initiated BLA submission to the Drug Regulatory Authority of Pakistan for the conditional approval of our PIKA rabies vaccine for post-exposure prophylaxis in November 2024. We decided to put the study on hold as we evaluate the commercial potential and regulatory requirements for the Southeast Asia region.

*Preclinical Study*

PIKA rabies vaccine has been extensively investigated in several animal models for immunogenicity and protective efficacy. In post-exposure efficacy test, groups of hamsters were infected with lethal dose of wild type BD06 strain rabies virus followed by immunization with normal saline, human rabies immunoglobulin (HRIG), vaccine control of standard regimen (days 0, 3, 7, 14 and 28), PIKA rabies vaccine of standard regimen, and PIKA rabies vaccine of accelerated regimen (double dose on days 0, 2 and single dose on day 7) respectively. The results showed PIKA rabies vaccine administered using a standard regimen conferred a 66.7% survival rate and 80% with an accelerated regimen, compared to a 20% survival rate provided by standard regimen of commercially available rabies vaccine (Figure 2). Animal studies have shown that administration of PIKA rabies vaccine using accelerated regimen results in improved survival in infected mice and high levels of neutralizing antibody production as early as four days after immunization.

Figure 2. Survival rate after PEP by PIKA rabies vaccine in golden hamster

A diagram of a vaccination

AI-generated content may be incorrect.

Significant difference between survival curves was determined by the Chi-square test (\*\*\**p* < 0.005). There is no significant difference between the groups not marked.

To further evaluate the efficacy of PIKA rabies vaccine, the representative strains of seven major rabies virus populations in the world were used as challenge viruses to challenge mice. In each challenge study with variants of street rabies virus, groups of mice were challenged with lethal dose of different strain rabies virus followed by immunization with PBS, Commercial Rabies Vaccine of standard regimen (days 0, 3, 7, 14 and 28), and PIKA rabies vaccine of accelerated regimen (double dose on days 0, 2 and single dose on day 7) respectively. The results showed that compared with the commercial rabies vaccine, the PIKA rabies vaccine could provide a more comprehensive protective effect, with a protective effect of more than 80% on all seven viruses (Table 2). In addition, PIKA rabies vaccine demonstrated quick onset of neutralization antibody titers and higher seroconversion rate at day 5 post the first dose injection of vaccines.

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*Phase I Clinical Trial in Singapore*

The Phase I clinical trial of PIKA rabies vaccine was conducted in Singapore. The study was a single-center, open label, randomized study in healthy naive adult subjects to determine the safety and immunogenicity of PIKA rabies vaccine. A total of 37 subjects were enrolled and randomly assigned to receive Rabipur, standard PIKA rabies vaccine and accelerated PIKA rabies vaccine. The vaccine dosage of Phase I clinical trial in Singapore was 1.0 mL. Rabipur marketed by Novartis is a commercialized rabies vaccine which was produced using Flury LEP rabies virus strain grown in a culture of primary chick embryo fibroblast cells. The dosing regimen for Rabipur recommended by the United States Centers for Disease Control and Prevention is four doses which are to be administered on days 0, 3, 7 and 14. No deviation from such approved regimen, including accelerated regimen, was allowed in humans with respect to Rabipur.

Figure 3

A diagram of a group of people

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The groups of Rabipur and standard PIKA rabies vaccine followed the same vaccine regimen (1-1-1-1), where one injection on days 0, 3, 7 and 14 each was administered. The group of accelerated PIKA rabies vaccine received the accelerated regimen (2-2-1), where two injections on both days 0 and 3 were administered in different arms, and only one injection was administered on day 7. Seroconversion is defined as post-vaccination serum rabies virus neutralizing antibody (RVNA) titer equal to or higher than 0.5 IU/mL, while the RVNA is absent in pre-vaccination serum. Such seroconversion as defined in our clinical trials is in line with those of other clinical trials for rabies vaccines. The Phase I clinical trial has demonstrated that, on day 7 under same 1-1-1-1 dosing regimen, only 16.7% of subjects receiving Rabipur seroconverted compared to 50% of subjects receiving PIKA rabies vaccine. Under the accelerated regimen, the PIKA rabies vaccine had a higher seroconversion rate with 75% by day 7, significantly higher than the control arm vaccine under the classic regimen. In addition to achieving higher immunogenicity, PIKA rabies vaccine elicited CD4 mediated T cell response detectable as early at day 7 which was maintained at day 42. No death or serious adverse events were reported in this trial. All adverse events in both the PIKA vaccine arms and the Rabipur arm are mild in severity. The incidence of adverse events is comparable between the PIKA vaccine arms and the Rabipur arm. The result has showed that PIKA rabies vaccine is safe and well tolerated. The following table sets forth the Phase I clinical results in Singapore concerning adverse events.

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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **System Organ Class (SOC)** |  | **Preferred term (PT)** |  |  | **Rabipur N=l2** |  |  |  | **PIKA Rabies Vaccine (1-1-1-1) N=l3** |  |  |  | **PIKA Rabies vaccine (2-2-1) N=l2** |  |
|  |  |  |  |  | **(in n(%))** |  |  |  | **(in n(%))** |  |  |  | **(in n(%))** |  |
| Gastrointestinal disorders |  | Diarrhoea |  |  | 1 (8.33 | )% |  |  | 0 (0.00 | )% |  |  | 1 (8.33 | )% |
|  |  | Nausea |  |  | 0 (0.00 | )% |  |  | 1 (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| General disorders and administration site conditions |  | Induration |  |  | 1 (8.33 | )% |  |  | 0 (0.00 | )% |  |  | 0 (0.00 | )% |
|  |  | Fatigue |  |  | 1 (8.33 | )% |  |  | 0 (0.00 | )% |  |  | 0 (0.00 | )% |
|  |  | Injection site pain |  |  | 0 (0.00 | )% |  |  | 6 (46.15 | )% |  |  | 3 (25.00 | )% |
|  |  | Injection site swelling |  |  | 0 (0.00 | )% |  |  | l (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  | Pyrexia |  |  | 0 (0.00 | )% |  |  | l (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Infections and infestations |  | Lymph gland infection |  |  | 1 (8.33 | )% |  |  | 0 (0.00 | )% |  |  | 0 (0.00 | )% |
|  |  | Pyuria |  |  | 0 (0.00 | )% |  |  | 2 (15.38 | )% |  |  | 1 (8.33 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Investigations |  | Glucose urine present |  |  | 0 (0.00 | )% |  |  | 2 (15.38 | )% |  |  | 0 (0.00 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Musculoskeletal and connective tissue disorders |  | Myalgia |  |  | 0 (0.00 | )% |  |  | 0 (0.00 | )% |  |  | 1 (8.33 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Nervous system disorders |  | Dizziness |  |  | 0 (0.00 | )% |  |  | 1 (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  | Headache |  |  | 0 (0.00 | )% |  |  | 1 (7.69 | )% |  |  | 1 (8.33 | )% |
|  |  | Lethargy |  |  | 1 (8.33 | )% |  |  | 0 (0.00 | )% |  |  | 1 (8.33 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Renal and urinary disorders |  | Proteinuria |  |  | 0 (0.00 | )% |  |  | 2 (15.38 | )% |  |  | 0 (0.00 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Respiratory, thoracic and mediastinal disorders |  | Cough |  |  | 0 (0.00 | )% |  |  | 1 (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Skin and subcutaneous tissue disorders |  | Hyperhidrosis |  |  | 0 (0.00 | )% |  |  | 1 (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  | Pruritus |  |  | 0 (0.00 | )% |  |  | 1 (7.69 | )% |  |  | 0 (0.00 | )% |
|  |  | Urticaria |  |  | 0 (0.00 | )% |  |  | 0 (0.00 | )% |  |  | 1 (8.33 | )% |
| Total number of subjects with at least one adverse event |  |  |  |  | 5 (41.67 | )% |  |  | 9 (69.23 | )% |  |  | 6 (50.00 | )% |

Figure 4. Percentage of subjects with protective serum neutralizing antibodies (≥0.5 IU/mL)

A graph of different colored bars

AI-generated content may be incorrect.

Significant difference between seroconversion rate was determined by Fisher’s exact test (\**p* < 0.05). There is no significant difference between the groups not marked.

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At the last visit day (day 42), the levels of neutralizing antibody titer in PIKA rabies groups, being administered under either the 1-1-1-1 or the 2-2-1 regimen, were comparable to that of the control group. The follow table sets forth the levels of neutralizing antibody titer on day 42 in Phase I clinical trial in Singapore.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Rabipur** |  | **PIKA Rabies Vaccine (l-1-1-1)** |  | **PIKA Rabies Vaccine (2-2-1)** |
|  |  | **mean ± standard deviation 95% confidence interval** |  | **mean ± standard**  **deviation 95% confidence internal** |  | **mean ± standard deviation 95% confidence internal** |
| **Neutralizing antibody titer** |  | 9.72 ± 11.66 |  | 12.07 ± 10.07 |  | 20.06 ± 33.12 |
|  |  | (-2.67, 22.11) |  | (-0.31, 24.46) |  | (8.26, 33.04) |

*Phase II Clinical Trial in Singapore*

Phase II clinical trial was conducted in two hospitals in Singapore. It was a multi-center, open label, randomized, non-inferiority study in healthy naive adult subjects to evaluate the efficacy and safety of the PIKA rabies vaccine under an accelerated regimen. 126 participants were enrolled and randomized into two groups, receiving Rabipur and PIKA rabies vaccine. PIKA rabies vaccine recipient achieved higher seroconversion rate (57.6%) at day 7 as compared to Rabipur (43.8%). All subjects in both PIKA rabies vaccine and Rabipur groups achieved seroconversion. The primary endpoint of non-inferiority was met.

Phase II clinical trial further supported the efficacy of the PIKA rabies vaccine under accelerated regimen, with earlier and higher production of neutralizing antibody as early as seven days after vaccination. Consistent with the adverse events findings in Phase I, no death or serious adverse events were reported in this trial. The majority of adverse events in the clinical trials conducted on PIKA rabies vaccine are mild to moderate in severity. The incidence of adverse events is comparable between the PIKA rabies vaccine arm and the Rabipur arm. The safety and tolerability profile of the PIKA rabies vaccine in such large sample size trial was comparable to that of Rabipur.

Figure 5

A diagram of a group of people

AI-generated content may be incorrect.

Figure 6. Percentage of subjects with protective serum neutralizing antibodies

(≥0.5 IU/mL)

A graph of red and blue bars

AI-generated content may be incorrect.

Significant difference between seroconversion rate was determined by Fisher’s exact test. There is no significant difference between the groups.

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At the last visit day (day 42), the level of neutralizing antibody titer in PIKA rabies group was comparable to that of the control group. The follow table sets forth the levels of neutralizing antibody titer on day 42 in Phase II clinical trial in Singapore.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Rabipur** |  | **PIKA Rabies Vaccine (2-2-1)** |
|  |  | **mean ± standard deviation 95% confidence**  **interval** |  | **mean ± standard deviation 95% confidence interval** |
| Neutralizing antibody titer |  | 19.16 ± 13.53 |  | 21.59 ± 46.90 |
|  |  | (15.69, 22.62) |  | (9.15, 34.04) |

The standard deviation of the neutralizing antibody titers in PIKA rabies vaccine arm appears to be wider due to one outlier which is beyond the upper test limit. The protection level of rabies vaccine is generally considered to be reached once neutralizing antibody titer reaches 0.5 IU/mL.

The accelerated regimen of PIKA rabies vaccine is advantageous to the standard Zagreb or Essen regimens because the standard regimens fail to induce higher and earlier seroconversion at day 7 post vaccination. Since the incubation period of rabies is approximately two or three months, our future clinical studies will evaluate the neutralizing antibody titers beyond 42 days, up to six and 12 months, respectively, and we will compare the antibody titers at different time points after vaccination between PIKA rabies vaccine and the commercialized rabies vaccines in comparison.

*Phase I Clinical Trials in China*

To re-confirm the dosage and regimen selected in Singapore trial to apply to the population in China, a Phase I study was designed and is being conducted in China to evaluate the safety and immunogenicity of PIKA rabies vaccine administered at different dosage and various dosing regimen.

A total of 96 subjects were enrolled in Phase I clinical trial. Two dose levels, 0.5mL and 1.0mL of PIKA rabies vaccine were evaluated using 2-1-1 regimen given on day 0, 7 and 21 (approved regimen for the currently marketed rabies vaccine). Four different dosing regimens were evaluated, including 2-1-1 regimen given on day 0, 7 and 21, 2-1-1 regimen given on day 0, 3 and 7, 2-2-1 regimen given on day 0, 3 and 7, 2-2-1 regimen given on day 0, 2 and 7. The design of Phase I clinical trial includes (1) the primary safety and immunogenicity endpoints, and (2) the secondary endpoint of antibody level, seroconversion and cellular immunity. The primary safety endpoints include: (1) solicited adverse events collected seven days after each vaccination, (2) unsolicited adverse events collected 49 days after the first immunization, and (3) serious adverse events on throughout the study. The primary immunogenicity endpoint includes seroconversion rate at predefined time points post vaccination. The secondary endpoint is measured by the antibody titers at different time points post immunization.

Figure 7

A diagram of a group of people

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No safety concerns were revealed. No deaths and serious adverse events were reported. No vaccine-related grade 3 adverse events were reported. The Phase I findings are consistent with those from Singapore trials and further demonstrates the capability of PIKA rabies vaccine of rapid and robust antibody response.

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Preliminary results of Phase I study of PIKA rabies vaccine in China confirmed the dose, regimen and safety observed from the Singapore trials. The early seroconversion is clinically meaningful, given that in the event of grade 3 exposure without administration of immunoglobulin, early seroconversion is a principal indication of the early presence of protective neutralizing antibody in the blood.

*Phase III Clinical Trial Plan in Pakistan and the Philippines*

A phase III, randomized, comparator-controlled, double-blind, multicenter study was designed to evaluate the immunogenicity, safety and lot to lot consistency of three lots of a PIKA Adjuvanted inactivated rabies vaccine in healthy adults using a post-exposure prophylaxis schedule. The clinical study is a multi-center, multi-country trial being conducted in Pakistan and the Philippines, which started in the second half of 2023.

Primary immunogenicity objectives of the study consist of demonstration of immunologic non-inferiority of PIKA rabies vaccine to the comparator Rabipur (or Rabipur equivalent) as measured by GMTs of RVNA and seroconversion rate differences at Day 14 and Day 28 and demonstration of lot-to-lot consistency of 3 production lots of PIKA rabies vaccine as measured by RVNA GMTs at Day 14. Co-primary safety objectives will include evaluation of all safety data collected from the study including changes in safety laboratory parameters from baseline. Secondary objectives include demonstration of immunological superiority of PIKA rabies vaccine to Rabipur as measured by seroconversion rate differences at Day 7 and evaluation of immune persistence of PIKA rabies vaccine as compared to the comparator vaccine.

In this study, a total of 4,500 randomized subjects has been enrolled with 3,000 subjects allocated to PIKA rabies vaccine and 1,500 allocated to receive the comparator rabies vaccine Rabipur. The following table sets forth each class of subjects and the respective allocated study days of vaccination.

Figure 8

A table with numbers and symbols

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The results of this Phase III clinical trial have met the primary endpoints of the trial, demonstrating its potential to achieve accelerated protection and meet the WHO’s goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens.

***PIKA YS-HBV-001***

PIKA YS-HBV-001 is a hepatitis B vaccine composed of genetically engineered recombinant hepatitis B surface antigen protein (HBsAg) and PIKA adjuvant, with the potential to become a hepatitis B vaccine with accelerated regimen. We have completed the Phase I clinical trial of PIKA YS-HBV-001 in Singapore in 2017, which has demonstrated good reactogenicity and tolerability and immunogenicity under accelerated regimen.

*Mechanism of action*

HBV infection can cause morbidity and mortality, including acute hepatitis necrosis and chronic active hepatitis. Patients with chronic HBV infection are at higher risk of cirrhosis and hepatocellular cancer. A concentration of antibody against HBsAg 10 mIU/mL can confer protection against HBV infection. PIKA YS-HBV-001 can elicit high-level specific antibodies and robust and multifunctional cellular immune response to prevent HBV infection. PIKA adjuvant acts as an immunomodulating agent on innate immune receptors for sensing the presence of virus infection. Those receptors are expressed in dendritic cells (DCs), which are the most potent antigen presenting cells. When combining PIKA with HBsAg in PIKA YS-HBV-001, PIKA activates DCs to secret interferon and cytokines, converts immature DCs to mature DCs for efficiently presenting HBsAg antigen to CD4+ T cells, and promotes T cell differentiation to functional helper T (Th) cells. Those helper T cells in turn provide multiple signals to B cells specific for HBsAg, generating antibody responses to provide protective immunity to HBV. Long-lived antibody response and T and B cell memory are able to provide persistent protection against HBV infection.

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*Market opportunity and competition*

Hepatitis B is an infectious illness caused by HBV, which infects the liver and causes inflammation, scarring and, in some cases, liver cancer. The disease is a major health concern worldwide, particularly in Asia and Africa. Common prevention methods for HBV includes HBV preventative vaccines, antiviral prophylaxis during pregnancy, screening of donated blood and HBV diagnosis.

According to the Global Hepatitis Report 2017 issued by the WHO, 257 million people, or 3.5% of the world population, was living with chronic HBV infection, and 0.9 million people died due to the complications of chronic HBV infections in 2015. In addition, certain chronic patients may develop cirrhosis, liver failure or hepatocellular cancer. An estimated 600,000 people die each year due to chronic consequences of HBV infection, such as cirrhosis and hepatocellular cancer, in addition to the approximate 40,000 deaths from the acute illness, according to the same source.

The high prevalence of infection has prompted the Chinese government to increase its efforts in treating those suffering from chronic hepatitis B and strengthen its hepatitis B immunization program. In addition, the current diagnosis and treatment rate in China is relatively low at 32.1% and 21.1% in 2019, respectively. Lot release of hepatitis B prophylactic vaccine in China was 70.7 million in 2021, and is expected to reach 85.4 million in 2025 and further to 90.8 million in 2030, according to the same source.

We believe PIKA YS-HBV-001 has advantages over current available hepatitis B vaccines in the market. See “—Our Marketed Product and Product Candidates—Our Clinical Stage Product Candidates—PIKA YS-HBV-001—Advantages.” We have completed the Phase I clinical trial of PIKA YS-HBV-001 in Singapore. We plan to proceed with more advanced clinical studies in China and other countries.

*Advantages*

The major marketed prophylactic hepatitis B vaccine products in China contain a recombinant HBsAg with an aluminum salt, and are administered as a series of three doses over six months. Most adults who did not receive hepatitis B vaccination as an infant or adolescent may be at risk of being infected with HBV. However, the challenge of successful vaccination of adults against HBV remains, including poor adherence to a complete three-dose vaccination schedule over six months and low protective antibody production especially when the full course of vaccination cannot be achieved. The current hepatitis B vaccines have the following limitations:

|  |  |  |
| --- | --- | --- |
|  | ● | *Low protective antibodies.* The existing prophylactic hepatitis B vaccine failed to induce sufficient protective antibodies in some individuals. Certain patient cohorts are more susceptible to hepatitis B and do not respond well to standard vaccination programs. End-stage renal disease patients on hemodialysis have a higher prevalence of HBV infection and poorer prognosis than the general population. However, vaccination against HBV proposed for uremic patients or pre-transplant patients shows vaccine seroconversion rates significantly lower than immunocompetent individuals. Even at anti-hepatitis B antibody protective levels, this patient population has lower peak antibody titers and lower hepatitis B antibody levels as well as shorter duration of immunity. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Long-term and overall low success rates.* Current prophylactic hepatitis B vaccines for adults usually require three doses given over six months to provide seroconversion of approximately 30%, 70% and 90% after the first, second and third dose, respectively. The effectiveness of current vaccines is further compromised because many people fail to receive all three doses. Vaccine is less effective in patients that are already on dialysis and a protective anti-hepatitis B level develops in only approximately 55% of recipients when the 40 ug dose (double dose) regimen is used. |

To overcome the limitations of the current vaccines, we developed PIKA YS-HBV-001 to reduce regimen duration and confer comparable or better protection against HBV infection. Two doses of HBV-001 given within one month will also potentially improve the compliance and reduce the cost of immunization. In preclinical studies comparing vaccines of HBsAg, we demonstrated that our PIKA-adjuvant PIKA YS-HBV-001 increased the production of HBsAg antibodies as compared with aluminum-adjuvant HBsAg vaccine. PIKA YS-HBV-001 enhanced T cell mediated immune response in mice and was able to induce the production of IFN-I’ secreting CD4+ and CD8+ T cells. The immune effect of PIKA YS-HBV-001 is superior to the existing non-adjuvant vaccine and alum- adjuvant vaccine. Moreover, PIKA YS-HBV-001 may realize multi-functional T cell induction. Phase I clinical studies have demonstrated that PIKA YS-HBV-001 has the potential to induce the production of multi-functional T cells in human, compared to Engerix, a marketed product, which primarily induced mono-functional T cells. The production of multi-functional T cells enables PIKA YS-HBV-001 to induce more robust and lasting T cell response, promote IFN and cytokine production and achieve accelerated and high seroconversion.

*Summary of preclinical and clinical results*

PIKA YS-HBV-001 completed the Phase I clinical trial in Singapore with 32 healthy naive adult subjects enrolled in the study.

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*Preclinical study*

The results from Balb/c mice study comparing vaccines of HBsAg without adjuvant and vaccines with alum-adjuvant HBsAg indicated that PIKA YS-HBV-001 substantially increased HBsAg-specific IgG production in mice compared with those immunized with HBsAg alone or with HBsAg plus alum adjuvant (p<0.05). In addition, YS-HBV-001 enhanced T cell mediated immune response in mice and was able to induce the production of IFN-I’ secreting CD4+ and CD8+ T cells. The immunogenicity of PIKA YS-HBV-001 was superior to the existing adjuvant-free vaccine and alum-adjuvant vaccine. PIKA YS-HBV-001 was well tolerated in rhesus monkeys and showed good immunogenicity.

Figure 23. IFN-γ Secreting T Cells by ELISpot after vaccination in mice

A comparison of a graph

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Figure 18. Anti-HBsAg antibody titers after vaccination in mice

A graph of different colored bars

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*Phase I clinical trial*

The Phase I clinical trial of PIKA YS-HBV-001 was conducted in Singapore to evaluate the safety and immunogenicity of PIKA YS-HBV-001. This study was a randomized, double blind, active control and parallel group study with the enrollment of 32 healthy naive adult subjects aged from 21 to 65 years. Three groups were enrolled in this study, including (1) half dose (20 ug HBsAg) plus 500 ug PIKA dosed on days 0, 28 and 56; (2) normal dose (40 ug HBsAg) plus 1000 ug PIKA dosed on days 0, 28, and 56, and (3) an Engerix comparator, namely 20 ug HBsAg plus 500 ug alum dosed on days 0, 28 and 168. The study has shown that the seroconversion rate was comparable between shortened regimen of PIKA YS-HBV-001 and the standard regimen of commercially available vaccine (ENGERIX-B vaccine) in the control arm. No death and no vaccine-related serious adverse events were reported. No clinically meaningful changes were identified in biochemical, hematological, vital signs and physical examination. The data indicate that PIKA YS-HBV-001 has a good safety and tolerability profile. There was also indication that higher seroconversion could be induced earlier by PIKA YS-HBV-001 than ENGERIX-B vaccine. PIKA YS-HBV-001 was also able to induce a higher magnitude, more robust and lasting T cell response compared to ENGERIX-B vaccine. In particular, PIKA YS-HBV-001 at normal dose can induce multi-functional T cells, which are considered significant in clearing virus-infected cells. PIKA YS-HBV-001 has similar safety and tolerability as compared to the commercially available vaccine in the control arm. The following table sets forth the seroconversion rate at different time points after vaccination with PIKA YS-HBV-001 or ENGERIX-B.

Figure 24. Percentage of vaccines producing cytokines upon single peptide stimulation

A graph of different colored squares

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit (Day)** |  | **Seroconversion Rate (%) Low dose HBV-001** | |  |  | **High dose HBV-001** | |  |  | **ENGERIX-B** | |  |
| Baseline |  |  | 0 |  |  |  | 0 |  |  |  | 0 |  |
| D 56 |  |  | 87.5 |  |  |  | 100 |  |  |  | 66.7 |  |
| D 84 |  |  | 90 |  |  |  | 100 |  |  |  | 66.7 |  |
| D 196 |  |  | 90 |  |  |  | 100 |  |  |  | 88.9 |  |

***PIKA YS-ON-001***

PIKA YS-ON-001 is a multiple component complex of proteins and PIKA that can reduce the immunosuppressive effect of the tumor microenvironment and enhance the anti-tumor activity of the immune system against tumor cells. We are currently independently developing PIKA YS-ON-001 as an immuno-oncology therapeutic. PIKA YS-ON-001 has demonstrated, in multiple animal models, strong anti-tumor activities as a standalone therapy and when combined with other therapeutic agents, such as kinase inhibitors, antibody blocking programmed death receptor-1 (PD-1) against a slew of advanced solid tumors, including hepatocellular cancer, breast cancer, lung cancer, colorectal cancer and prostate cancer. The U.S. FDA also granted PIKA YS-ON-001 two ODDs for the treatment of pancreatic cancer and hepatocellular cancer.

With respect to PIKA YS-ON-001, we completed the Phase I clinical study in China in 2023, focusing on the safety study on late-stage breast cancer, lung cancer, liver cancer and melanoma subjects. PIKA YS-ON-001 showed good safety and tolerability among cancer patients in the Phase I clinical study. We are currently evaluating its future development plans.

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*Mechanism of action*

The effectiveness of immuno-oncology therapy often depends on the interaction of tumor cells with immune regulation within the tumor microenvironment. Under these interactions, the tumor microenvironment plays an important role in inhibiting or enhancing the immune response. We believe that an effective immunotherapy against cancer requires multimodal approaches that target different aspects of the antitumor response (see Figure 6), such as tumor antigen recognition, T cell activation, NK cell activation and blockade of immune inhibitory pathways.

Figure 25. Multimodal approaches of cancer immunotherapy

A diagram of cell division

AI-generated content may be incorrect.

PIKA YS-ON-001 is our proprietary immunotherapeutic agent based on the TLR3/RIG- I/MDA5 signaling pathway of PIKA immunomodulating technology. It can enhance the phagocytosis of macrophages, upregulate the activation of DC cells, NK cells and T cells, induce the production of multiple tumor-inhibitory cytokines and tumor cell apoptosis, and improve the host immune response. The effectiveness of immuno-oncology therapy often depends on the interaction of tumor cells with immune regulation within the tumor microenvironment. Under these interactions, the tumor microenvironment plays an important role in inhibiting or enhancing the immune response. We believe that an ideal immunotherapy against cancer requires multimodal approaches that target different aspects of the antitumor response, such as tumor antigen recognition, T cell activation, NK cell activation and blockade of immune inhibitory pathways. Preclinical tumor microenvironment immune regulatory studies have shown that besides of increasing CD4+ and CD8+ T cell responses, PIKA YS-ON-001 can also significantly increase the proportion of NK and NKT cells in the tumor microenvironment. In several tumor models, PIKA YS-ON-001 can significantly reduce the number of Tregs in tumor microenvironment. At the same time, YS-ON-001 can reprogram tumor-associated macrophages (TAMs) from a protumor M2 phenotype to an antitumor M1 phenotype. The studies have indicated that YS-ON-001 could weaken the immunosuppressive effect of tumor microenvironment and enhance the killing function of immune system to tumor cells. With the multiple modes of action of PIKA YS-ON-001, we believe PIKA YS-ON-001 has the potential to become an integral immunotherapy component with standard of care chemotherapies, targeted therapies and checkpoint inhibitors or with other emerging immunotherapies that produce additive or synergistic treatment benefits.

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Figure 26. Frequency of immune cells in EMT-6, Hepa 1-6, and H22 tumors from mice

A group of graphs showing different types of vehicles

AI-generated content may be incorrect.

Data are shown as mean ± SEM. Significance was calculated using unpaired *t*-test (\**p* < 0.05, \*\**p* < 0.01).

EMT-6: mouse breast cancer cell; Hepa 1-6: mouse liver cancer cell; H22: mouse liver cancer cell

*Market opportunity and competition*

The incidence of pancreatic cancer in China increased from approximately 101,500 in 2017 to approximately 115,900 in 2021, and is expected to reach approximately 155,800 in 2030, according to the same source. According to the WHO, the number of new cases is expected to rise by approximately 70% over the next two decades.

Immuno-oncology is a rapidly growing field in cancer treatment that focuses on modulating the immune system to stimulate or enhance anti-tumor activities to inhibit growth or eliminate tumors. Multiple strategies and technologies have been explored to enhance and prolong anti-tumor immune responses. Agents that inhibit two of these immune checkpoints, CTLA-4 and the PD-1/PD-L1 interaction, have recently been approved for a number of cancer indications. These checkpoint inhibitors represent a major advancement in cancer treatment, but a majority of patients fail to respond to these inhibitors used as single agents, which represents a significant opportunity to develop new immunotherapy with multiple immunomodulating functions in order to change the tumor microenvironment, enabling remission and durable control of tumor growth.

*Advantages*

Current available immune-oncology therapeutic biologics in China and global markets mainly include monoclonal antibodies, bispecific antibodies, cytokines and therapeutic cancer vaccines. Our research has indicated that PIKA YS-ON-001 has the following potential advantages and benefits that differentiate it from currently available immuno-oncology therapeutic biologics:

|  |  |  |
| --- | --- | --- |
|  | ● | *Broad spectrum of anti-tumor activity*. Unlike PD-1 related checkpoint inhibitors, which tend to be more effective among patients with high PD-L1 expression on tumor cells, PIKA YS-ON-001 is a multi-target immuno-oncology drug and offers broad spectrum of anti-tumor activities, including hepatocellular cancer, lung cancer, breast cancer, colorectal cancer, prostate cancer, pancreatic cancer, lymphoma and melanoma. Figure 8 below (not head-to-head) represented the tumor growth inhibition (TGI) of multiple mice tumor models treated with PIKA YS-ON-001, anti-PD-1 or anti-PD-L1 antibodies. Treatment with PIKA YS-ON-001 significantly lowered the tumor weight and resulted in >50% inhibition rate, which was more efficient than anti-PD-1 or anti-PD-L1 antibodies. |

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Figure 9 below showed enhanced anti-cancer activity of PIKA YS-ON-001 when in combination with anti-PD-1 antibody.

Figure 27. TGI of mouse tumor models treated with PIKA YS-ON-001, anti-PD-1 or anti-PD-L1

A group of blue and yellow graphs

AI-generated content may be incorrect.

Figure 28. Enhanced anti-tumor activity of PIKA YS-ON-001 with anti-PD-1 antibody

A graph of a number of patients with cancer

AI-generated content may be incorrect.

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Data are shown as mean ± SEM. *P*-values were analyzed with a two-way ANOVA (\*\**p* < 0.005, \*\*\**p* < 0.001)

|  |  |  |
| --- | --- | --- |
|  | ● | Potential to be used in combination with cancer therapies available in the market. |

|  |  |  |
| --- | --- | --- |
|  | (1) | *Combination with radiotherapy (RT)*: RT has been one of the three major traditional treatments for cancer patients to provoke important responses not only at the site of treatment but also on remote, non-irradiated tumor deposit, namely the abscopal effect. Radiation damaged cells can activate antigen presenting cells and induce maturation of dendritic cell to efficiently present tumor antigen to T cells. In combination with RT, PIKA YS-ON-001 has the potential to act as immune-modulator to enhance tumor specific immune response. |

|  |  |  |
| --- | --- | --- |
|  | (2) | *Combination with targeted therapies*: Our study demonstrated that PIKA YS-ON-001 enhanced anti-cancer activity when combined with sorafenib, a multi-kinase inhibitor. We believe PIKA YS-ON-001 has the potential to be combined with various targeted therapies. |

|  |  |  |
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|  | (3) | *Combination with checkpoint inhibitors*: PIKA YS-ON-001 can enhance the PD-L1 expression in tumor cells, which in most tumors are favored for PD-1 blockers to achieve a high response rate. By combining PD-1 blockers, PIKA YS-ON-001 could enhance the therapeutic effect of PD-1 blocker, especially in those tumors that express no or low level of PD-L1 or are refractory to PD-1 blocker treatment. |

|  |  |  |
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|  | (4) | *Combination with oncolytic viruses*: Oncolytic virus therapy is emerging as a new approach in cancer treatment and oncolytic viruses are self-replicating, tumor selective and can directly lyze cancer cells. The damaged tumor cells could activate specific immune response to tumors which could be leveraged by PIKA YS-ON-001 to further enhance immune responses. |

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|  | (5) | *Combination with chemotherapies*: PIKA YS-ON-001 could also be combined with chemotherapy. Tumor antigen released from damaged tumor cells upon exposure to cytotoxic therapeutic agents can be captured by PIKA YS-ON-001 activated DCs and enhance the overall anti-tumor effects. |

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|  | ● | *Potential to have better safety profile and marketability*. Adoptive cell-based immunotherapy, such as CAR-T and other in vitro modification of immunological cells, tends to have significant side effects, high level of technical complexity and difficulty in quality control and commercialization. Unlike these products, PIKA YS-ON-001 is expected to activate the patient’s own cellular immune response by modulating tumor microenvironment. We expect PIKA YS-ON-001 to have a better safety profile and marketability. |

*Summary of preclinical and clinical results*

*Preclinical results*

The following table summarizes the preclinical study results of PIKA YS-ON-001’s superior anti-tumor activities as compared to the standard cares of cancer treatment, measured by Treatment/Control (T/C)(%) and tumor inhibition rate (IR) of PIKA YS-ON-001 in advanced solid tumors animal models.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Animal Model** |  | **Agent** |  | **T/C(%)** | |  |  | **IR (%)** | |  |
| Breast cancer 4T1 in-situ model |  | PIKA YS-ON-001 |  |  | 45.87 |  |  |  | 42.26 |  |
|  |  | Docetaxel |  |  | 50.12 |  |  |  | 35.55 |  |
| Lewis lung cancer LL/2 transplanted tumor model |  | PIKA YS-ON-001 |  |  | 37.02 |  |  |  | 60.88 |  |
|  |  | Cisplatin PIKA |  |  | 47.46 |  |  |  | 42.38 |  |
|  |  | YS-ON-001 +Cisplatin |  |  | 28.38 |  |  |  | 75.44 |  |
| Liver cancer H22 transplanted tumor model |  | PIKA YS-ON-001 |  |  | 18.84 |  |  |  | 73.40 |  |
|  |  | Sorafenib PIKA |  |  | 36.79 |  |  |  | 53.73 |  |
|  |  | YS-ON-001+Sorafenib |  |  | 12.56 |  |  |  | 88.19 |  |
| Colon cancer CT-26 transplanted tumor model |  | PIKA YS-ON-001 |  |  | 5.38 |  |  |  | 97.71 |  |
|  |  | PD-1 |  |  | 53.66 |  |  |  | 47.05 |  |
| Prostate cancer RM-1 transplanted tumor model |  | PIKA YS-ON-001 |  |  | 1.39 |  |  |  | 98.56 |  |
|  |  | PD-1 |  |  | 57.62 |  |  |  | 38.12 |  |
| Melanoma B16-F10 Metastatic tumor model |  |  |  |  |  |  |  |  |  |  |

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*Phase I clinical trial*

The Phase I clinical trial of PIKA YS-ON-001 is an open label, dose escalation and cohort expansion study in patients with advanced solid tumors. The objective of the Phase I clinical trial is to evaluate the safety and tolerability of YS-ON-001 in patients with advanced solid tumors who have limited available treatment options. Three dose levels were evaluated in a dose escalation fashion. We commenced the cancer patient enrollment for the Phase I clinical study in China in December 2021, focusing on the safety study on late-stage breast, lung, liver and melanoma subjects. We have completed Phase I clinical study in China in 2023.

***PIKA YS-HBV-002***

PIKA YS-HBV-002 is being developed as an immune-therapy vaccine to treat chronic HBV infection, a significant unmet medical need worldwide. YS-HBV-001 contains PIKA adjuvant and HBV surface antigen, whose primary indication is the prevention of HBV infection. In contrast, PIKA YS-HBV-002 contains PIKA adjuvant and multiple HBV antigens, whose primary indication is the treatment of patients with chronic hepatitis B. Leveraging our proprietary PIKA immunomodulating technology in developing PIKA YS-HBV-001, PIKA YS-HBV-002 seeks to control and eliminate HBV from infected patients, which cannot be achieved through currently available anti-viral drugs. It is now widely accepted that to cure HBV, immune-based intervention will play an essential role in addition to the current antiviral approaches. The importance of T cells in establishing a functional cure of chronic HBV infection is a well-established concept based on human and animal data. HBV-specific T cells are quantitatively and functionally defective in CHB patients. The role of natural killer cells is also reported to play a protective role in the control of HBV replication. Our PIKA immunomodulating technology has the potential to generate potent activators of both T and NK cells and a strong inducer of interferon production, which makes PIKA adjuvant suitable to be integrated into a therapeutic HBV vaccine. The following figure shows the preliminary anti-viral result of PIKA YS-HBV-002.

Figure 29. Decline in HBV DNA by HBV-002 in transgenic mice

A graph of a number of objects

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Data are shown as mean ± SEM. Significance was calculated using unpaired *t*-test.

In September 2023, the United States Patent and Trademark Office issued a patent covering our PIKA YS-HBV-002, an immunotherapeutic vaccine designed to treat patients suffering from chronic hepatitis B virus infection. In April 2024, YS-HBV-002 immunotherapeutic vaccine, designed to treat patients suffering from chronic hepatitis B virus infection, has been granted clinical trial approval by the Philippine Food and Drug Administration. We have made a strategic decision to terminate the trial in order to allocate our resources to other priority initiatives.

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**Our Preclinical Stage Product Candidates**

***PIKA YS-ON-002***

PIKA YS-ON-002 is being developed as another immune-oncology therapy based on our PIKA immunomodulating technology platform. Compared with PIKA YS-ON-001, which is a composition of PIKA agent with immunogenic protein-based antigens and other expedients, PIKA YS-ON-002 is a composition of PIKA agent, stabilization agent and other expedients. PIKA YS-ON-002 has a broad spectrum of anti-tumor activity against many tumor types, such as liver, colon, breast, lung, prostate, kidney, lymphoma and pancreatic cancer. We believe that PIKA YS-ON-002 will have significant synergistic effect when combined with other treatment modalities such as chemotherapies, radiation therapies, checkpoint inhibitors and kinase inhibitors, leading to broad market opportunities.

PIKA YS-ON-002, when administered subcutaneously once a week, has demonstrated anti-tumor activities with a tumor growth inhibition of 76.42% against pancreatic cancer in a mouse model. When given at higher doses, PIKA YS-ON-002 completely eradicated established tumors, and some animals remained tumor free even after the cessation of PIKA YS-ON-002. The low dose of PIKA YS-ON-002 achieved 40% tumor free.

Figure 30. Anti-tumor effects of PIKA YS-ON-002 on subcutaneous Pan02 Murine Pancreatic Cancer Model

A graph of a patient's growth

AI-generated content may be incorrect.

Data are shown as mean ± SEM. *P*-values were analyzed with a two-way ANOVA (\*\*\**p* < 0.001)

***PIKA Influenza Vaccine***

PIKA influenza vaccine is designed to contain quadrivalent seasonal inactivated influenza virus recommended by regulatory authorities regarding the annual seasonal vaccine. These inactivated influenza virus function as antigens which induce a humoral immune response, measured by hemagglutination inhibition (HI) antibody.

The addition of PIKA adjuvant may enhance the humoral and cellular immune responses. Specific levels of HI antibody titers induced by vaccination with recombinant HA protein vaccine have not been correlated with protection from influenza illness. In some human studies, HI antibody titers of 1:40 or greater have been associated with protection from influenza in up to 50% of subjects.

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Antibodies against one influenza virus type or subtype confer limited or no protection against another. Furthermore, antibodies to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype. Frequent (usually annual) development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual replacement of one or more influenza virus strains in each year’s influenza vaccine. Influenza vaccines are standardized to contain the hemagglutinins of influenza virus, representing the influenza viruses that are likely to be in circulation in the upcoming influenza season. Annual vaccination with the influenza vaccine is recommended because immunity during the year after vaccination declines, and circulating strains of influenza virus also change from year to year.

In a seasonal influenza mouse model, addition of PIKA was able to significantly enhance the antibody production via intranasal or subcutaneous administration of inactivated influenza vaccine, as compared to antigen alone. In an influenza virus challenge model, PIKA- adjuvanted influenza vaccine reduced the viral loads by 100-fold in the lungs, as compared to antigen alone. Antigen sparing effects by PIKA adjuvant were also demonstrated in a seasonal influenza mouse model that mixes PIKA with 0.015 ug of antigen dose which induced similar level of antibody responses to 1.5 ug antigen without adjuvant. In H5N1 pandemic influenza mouse model, PIKA-adjuvanted inactivated vaccine has demonstrated enhanced humoral immune responses and profound reduction of viral loads in the lungs. More importantly, using a lethal H7 influenza virus challenge model, mice vaccinated with inactivated H7N7 vaccine were completely protected against lethal challenge with H7N9 virus, which indicates clinical potential of the cross protection. In addition, with the potential of nasal application, PIKA influenza vaccines may have advantages compared to injectable-only vaccines such as better acceptance due to painless administration, additional protection by mucosal immunity and more user-friendly self-administration, especially during epidemics.

Figure 31. Pulmonary viral titer on day 5 post-infection in mice challenged with 50 PFU of PR8 intranasally three weeks after the boosting

A diagram of a patient's test results

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**Our Strategic Collaborations**

***Global Health Agreement with Adjuvant***

We entered into a global health agreement with Adjuvant Global Health Technology Fund, L.P. (“Adjuvant”), as amended, in connection with Adjuvant’s investment of $10.0 million in us. Adjuvant is an investment fund formed for the charitable purpose of improving global health through the provision of financing to address global health challenges by supporting the development, production and commercialization of drugs, vaccines, medical devices, preventatives, diagnostics and other related technology targeting neglected infectious diseases and other global health conditions impacting low- and middle-income countries as defined by the World Bank. Pursuant to the agreement, we undertook, with the funding support of $10.0 million from Adjuvant, to, among others, apply such funds to develop and commercialize YSJATM rabies vaccine in 31 low income and 47 lower-middle income countries as defined by the World Bank (the “Designated Markets”). We agreed to use commercially reasonable efforts to pursue WHO prequalification to make the vaccine eligible for purchase and delivery by United Nation agencies and make the vaccine available in sufficient volume to both public and private purchasers in the Designated Markets with a reasonable tiered pricing framework, determined with reference to the type of buyer and the geographical location of such buyer. Alternatively, we could satisfy the foregoing obligations by licensing or partnering with a third party that has the capabilities to develop and commercialize YSJATM rabies vaccine in the Designated Markets. The obligation has a term of seven years and will be terminated prior to such term when and if have licensed or partnered with a third party to discharge such obligations with the prior consent of Adjuvant. We also agreed to furnish certain periodical reports, including the use of the funding and the progress of the commercial objectives. If we fail to maintain compliance with these and other program-related investment commitments under such global health agreement, Adjuvant may be entitled to repayment for any portion of its investment that is not used for the purposes outlined in such agreement, the maximum amount of which is limited to Adjuvant’s investment of $10.0 million. As of the date of this Annual Report, Adjuvant’s investment has been fully utilized toward development of product pipelines as well as develop and commercialize YSJATM rabies vaccines overseas. In the event of the assignment, sale, exclusive license, or other transfer of intellectual property related to YSJATM rabies vaccines and related technology, we must ensure that the aforementioned commitments are expressly assumed by the purchaser, transferee, licensee, or acquirer. Upon the occurrence of certain events, including the failure, by us or any successor to prosecute related material intellectual property, to comply with the global health agreement, we agree to grant Adjuvant a nonexclusive, irrevocable, non-terminable, fully-paid up, royalty free license (with the right to sublicense to third parties) to YSJATM rabies vaccine to use, reproduce, modify, make, have made, distribute, sell and otherwise dispose of the product solely in the Designated Markets for the sole purpose of achieving the commitment under the global health agreement. The global health agreement has a term of seven years commencing July 10, 2020, and may be terminated earlier if we, with the prior consent of Adjuvant, out-license to a third party with the capabilities to develop and commercialize YSJATM rabies vaccine.

**Research and Development**

We believe our commitment to R&D of innovative products and technologies remains fundamental to our success. Our PIKA immunomodulating technology continues to underpin a robust pipeline of product candidates. Our R&D team drives all critical functions of the innovation pipeline, supported by strategic collaborations with top-tier academic institutions and industry experts. This integrated approach ensures alignment with scientific best practices and accelerates the translation of breakthrough technologies into market-ready products.

***PIKA Immunomodulating Technology Platform***

*Overview*

Our PIKA immunomodulating technology targets toll-like receptor-3 (TLR3), retinoic acid inducible gene-I (RIG-I), and melanoma differentiation-associated protein 5 (MDA 5), to activate the innate immune cells, such as antigen presenting cells and dendritic cells. The incorporation of our PIKA immunomodulating technology in our vaccines and therapeutic biologics achieved substantially enhanced immune responses as observed in both clinical and preclinical studies.

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Since we acquired PIKA immunomodulating technology in 2010, pursued in-house advancement of the PIKA technology in multiple fronts, including the following:

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| --- | --- | --- |
|  | ● | More in-depth understanding of the mechanism of action underlying the technology. We identified the capability of PIKA immunomodulating technology for T-cell activation in human clinical study, as well as the change of tumor cell micro- environment in the immuno-oncology field. Our findings in the immuno-oncology area established the anti-tumor mechanism of action in PIKA adjuvant, which laid a theoretical foundation for the application of PIKA adjuvant in tumor immunotherapy. |

|  |  |  |
| --- | --- | --- |
|  | ● | Developed clinical applications and expanded protection of IP. We developed the application of PIKA adjuvant into multiple areas, including rabies vaccines, prophylactic and therapeutic HBV vaccines and 33 immune-oncology. We obtained patents for such relating to both vaccine and anti-cancer fields in multiple jurisdictions. |

|  |  |  |
| --- | --- | --- |
|  | ● | Large-scale manufacturing technology of PIKA adjuvants. We established an automated process of PIKA synthesis with the scale of over 100 liter in size under the relevant GMP guidance, which is critical to the commercialization of PIKA- based vaccine and therapeutic candidates. |

We believe our PIKA immunomodulating technology has the potential to generate prophylactic and therapeutic vaccines. PIKA immunomodulating technology has already produced clinical stage candidates in three areas, including (1) PIKA rabies vaccine with significantly fast onset of seroconversion, ideally for three-visit one-week regimen to replace the existing five-visit one-month and three-visit three-week regimen, (2) emerging immune-oncology therapeutic biologics, including PIKA YS-ON-001 and PIKA YS-ON-002 with broad anti-cancer properties, and (3) HBV interventions, PIKA YS-HBV-001, a new preventive vaccine targeting two-visit one-month regimen to replace the existing three-visit six-month regimen, and PIKA YS-HBV-002, a therapeutic product to treat chronic HBV infection. See “—Our Marketed Product and Product Candidates—Our clinical stage product candidates” and “—Our Marketed Product and Product Candidates—Our preclinical stage product candidates.”

We obtained patents for our PIKA immunomodulating technology in more than 14 countries and regions. See “—Intellectual Property—Patents.”

In the United States, the NIH recognized the innovation and the potential of PIKA adjuvant in vaccine and other biologics fields and therefore has included PIKA adjuvant technology in the NIH vaccine adjuvant compendium, to promote scientific exchange and research collaboration around PIKA technology worldwide. The list includes scientific findings of PIKA adjuvant and data related to rabies virus, SARS-Cov-2 virus (recombinant protein), influenza A virus and hepatitis B virus.

*Mechanism of actions*

PIKA molecule is a class of double strand RNA (dsRNA) molecules of well-defined, specific ribonucleic acid units and molecular weight distribution synthesized with our proprietary technology. Endosomal dsRNA can be recognized by TLR3 while cytosolic dsRNA can be sensed by the retinoic acid-inducible gene (RIG) I-like receptor (RLR) family which include RIG-I and melanoma differentiation-associated protein 5 (MDA 5).

TLR3 is expressed primarily endosomal and in multiple cell and tissue types, including epithelial cells, muscle cells, certain neoplasms and antigen presenting cells; the RIG-I and MDA5 are ubiquitously expressed. Through TLR3, RIG-I and MDA5 signaling, PIKA can induce a prompt production of interferon, cytokines, chemokines and costimulatory factors. The anti-viral and anti-tumor effects of interferon have been well established and led to the U.S. FDA approval of several interferon-based products for antiviral and anti-tumor indications. In recent years, the U.S. FDA approved several TLR adjuvanted vaccines, including TLR4 based HPV vaccine (Cervarix) and zoster vaccine (Shingrix), and TLR9 based HBV vaccine (HEPLISAV-B). TLRs also attracted substantial interests in cancer research with emerging body of evidence indicating that strong innate and adaptive immune response induced by TLR activation could play a critical role in the cancer treatment. TLR based cancer monotherapy or combination therapies are currently in different phases of clinical development.

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Double-strand RNA stimulation can activate dendritic cells and upregulate the co- stimulatory and activation markers of dendritic cells such as CD86 and CD40. Dendritic cells play critical role in innate and adaptive anti-viral and anti-tumor immune responses.

Protein-based vaccine without proper adjuvant is poorly presented by dendritic cells to CD8 T cells which are essential for anti-viral and anti-tumor effect. The production of type I interferon upon PIKA stimulation facilitates antigen cross presentation by dendritic cells and augment CD8 T cell and NK cell responses, which makes protein-based vaccines suitable for viral clearance and as well as anti-tumor indications. DsRNA is also found to activate NK cells through TLR-TICAm-1 pathway, and decrease both regulatory T cells and myeloid-derived suppressor cells, which also provide rationale for integrating PIKA in anti-viral and anti-cancer treatment.

TLR3 is expressed by sentinel cells of the innate immune system such as dendritic cells, natural killer cells, and macrophages, and by nonimmune cells including epithelial cells, fibroblasts, and endothelial cells. TLR3 localizes to the endosomes where it senses viral and host-derived nucleic acids and initiates inflammatory pathways, activating the innate immune response and establishing an antiviral state to prevent viral replication. Its expression modulates rapidly in response to pathogens, various cytokines, and environmental stress.

TLR3 expression on immune cells has been widely exploited to promote an anti-tumor immune response, and various TLR3 agonists have been investigated in clinical trials for their anti-tumor immunity. The anti-tumor responses that are induced by TLR3 agonists are attributed to their capability to stimulate APCs, such as DCs, which in turn activate tumor specific T cell responses and to their capacity to switch the phenotype of myeloid suppressor cells and tumor associated macrophages from immunosuppressive to immunosupportive.

TLR3 signaling can also occur on nonimmune cells, contributing to an anti-tumor response. Many types of cancer express TLR3, including breast cancer, oral cell squamous and esophageal cancer, cervical cancer, ovarian cancer, prostate cancer, head and neck cancer, hepatocellular cancer and melanoma. Cancer cells respond to TLR3 ligands by secreting inflammatory cytokines, type I interferon, and chemokines, which enhance the recruitment and activation of immune cells.

Moreover, TLR3 agonists are found to promote the direct inhibition of tumor growth in vitro in several mouse and human cancer cell models through two mechanisms: decreasing proliferation and inducing apoptotic cell death.

***Research and development team and activities***

***In-house research and development team and activities***

As we engaged in both the manufacturing of YSJATM rabies vaccine and the continuous exploration of our PIKA-based candidate pipeline, R&D efforts span from those relating to our marketed product, in particular those relating to manufacturing technologies and quality assurance and control, to those relating our product candidates, such as PIKA adjuvant and relevant products.

Our R&D team consisted of 112 employees as of March 31, 2025, representing 19.5% of our total employees. Our R&D team is located in Beijing, Shenyang (China) and Philippines, involved in different stages of the R&D process relating to our marketed product and product candidates such as preclinical studies, clinical trials, regulatory filings and process development. Our core R&D staff also specialize in different aspects of our R&D initiatives, which consist of preclinical team, clinical team, regulatory filling team and intellectual property team. In addition, our quality management staff in Shenyang also supports our R&D by performing the related quality assurance and control activities.

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Our preclinical team is responsible for proof-of-concept, preclinical evaluation, establishment of manufacturing processes and formulation, quality research and method development. Our preclinical team is further divided into different R&D focuses, such as project, platform and culture collection, PIKA adjuvant, bioreactor and technology development. Our clinical team is primarily responsible for performing clinical trial study design and management. Our regulatory filing team is primarily responsible for vaccines and biologics approval process and monitoring our R&D projects to ensure their compliance with relevant regulations. Our intellectual property team is primarily responsible for patent and trademark application and maintenance, and they thoroughly communicate with technicians to conduct intellectual property retrieval and analysis.

***Outsourced research and development activities***

In line with industry practice, we outsource certain testing activities related to R&D to independent CROs. See “—CROs” for details. We cooperate with reputable organizations and institutions with respect to our outsourced R&D activities, which provide important access to human subjects and professional testing and clinical trial services. For instance, we cooperate with certain active hospital units in Singapore, which are operated under stringent standards and high efficiency, providing on-site support to investigators as well as safety, security and reassurance for study volunteers. We also cooperate with reputable institutions in China such as CDC, the Institute of Microbiology of the Chinese Academy of Sciences (IMCAS), the Kunming Institute of Zoology of the Chinese Academy of Sciences (KIZ) and the Institute of Laboratory Animal Science, Chinese Academy of Medical Sciences & Peking Union Medical College (CAMS&PUMC).

***Research facilities***

We have established two main R&D sites located in Beijing and Shenyang (China). We strategically allocate our R&D activities in different regions according to their respective advantages and resources. For example, we primarily carry out our late stage R&D activities relating to PIKA rabies vaccine in Shenyang facilities, leveraging our in-depth experience in pilot and large scale of manufacturing functions.

**Intellectual Property**

Our intellectual property and proprietary technology are important to our success. We rely primarily on a combination of patent, trademark and trade secret protection laws as well as employee confidentiality agreements to safeguard and protect our intellectual property rights and knowledge as well as our brand. Our ability to protect and use our intellectual property rights in the continued development and commercialization of our technologies and products, operate without infringing upon the proprietary rights of others, and prevent others from infringing our proprietary rights, is also crucial to our continued success. We will protect our products and technologies from unauthorized use by third parties only to the extent they are covered by valid and enforceable patents, trademarks or copyrights, or are effectively maintained as trade secrets, knowledge or other proprietary information. With respect to, among other things, proprietary knowledge that is not patentable and processes for which patents are difficult to enforce, we rely on trade secret protection and confidentiality agreements (or confidentiality provisions in employment contracts) to safeguard our interests. We believe many elements of our products, clinical trial data and manufacturing processes involve proprietary knowledge, technology or data that are not covered by patents or patent applications. We have taken appropriate security measures to protect these elements. In particular, we entered into confidentiality, non-compete and invention assignment agreements with our executive officers and R&D personnel. These agreements address intellectual property protection issues and require the employees to assign to us all of the inventions, designs and technologies they develop during their terms of employment and cooperate with us to secure patent protection for these inventions if we wish to pursue such protection. Any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any of our trade secrets, knowledge or other proprietary information that is not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be materially and adversely affected. Despite any measures we may take to protect our intellectual property, no assurance can be made that unauthorized parties will not attempt to copy aspects of our products or manufacturing processes or our proprietary technology, or to obtain and use information that we regard as proprietary. See “Item 3. Key Information—D. Risk Factors—Risks Related to Our Intellectual Property.”

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***Patents***

We actively seek for our PIKA immunomodulating technology and product candidates embodying the technology, and consider on a case-by-case basis filing patent applications with a view to protecting certain innovative products, processes, and methods of treatment (or other equivalents in certain jurisdictions). As of the date of this Annual Report, Singapore LakeShore is the proprietary owner of a vast majority of our patents owning about 46 patents in 14 countries and the term of individual patents may vary based on the countries in which they are obtained. The patent portfolios for our PIKA immunomodulating technology and major clinical stage product candidates as of the date of this Annual Report are summarized below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product/ technology** |  | **Patent name** |  | **Owner/ applicant** |  | **Jurisdiction** |  | **Patent status(1)** |  | **Patent expiration** |  | **Type of patent** |
|  |  |  |  | Singapore |  | South Africa |  | Granted |  | 2026 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| PIKA adjuvant |  | Mucosal Immunogenic substances comprising a polyinosinic acid- polycytidilic acid-based adjuvant |  | Yishengbio (Hong Kong) |  | South Africa |  | Granted |  | 2026 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | Liaoning Yisheng |  | China |  | Granted |  | 2026 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Method for reducing DNA impurities in viral compositions |  | Singapore LakeShore |  | The European Union, Switzerland, France, United Kingdom, Germany, Singapore, the United States |  | Granted |  | 2030 |  | Process/Method |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | Liaoning Yisheng |  | China |  | Granted |  | 2030 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| PIKA HBV |  | A composition for treating and/or preventing Hepatitis B virus infection |  | Singapore LakeShore |  | the United States, Cuba, India, Singapore, Vietnam |  | Granted |  | 2038 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | Singapore LakeShore |  | Australia, Canada, Brazil, India, New Zealand |  | Pending |  | N/A |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | Yishengbio (Hong Kong) |  | China, the European Union |  | Pending |  | N/A |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| PIKA rabies vaccine (Vero cell) |  | A composition comprising PIKA adjuvant |  | Singapore LakeShore |  | China, Indonesia, India, Russia, the Philippines, South Africa, the United States |  | Granted |  | 2034 to 2037 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | Yishengbio (Hong Kong) |  | China |  | Granted |  | 2034 |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product/ technology** |  | **Patent name** |  | **Owner/ applicant** |  | **Jurisdiction** |  | **Patent status(1)** |  | **Patent expiration** |  | **Type of patent** |
| PIKA YS-ON-001 (Cancer) |  | A composition comprising PIC for treatment of cancer |  | Singapore LakeShore |  | Mexico, South Africa, the United States |  | Granted |  | 2037 to 2038 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | HK Yisheng |  | the European Union (including France, and Germany), United Kingdom |  | Granted |  | 2037 to 2038 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | HK Yisheng |  | China |  | Pending |  | N/A |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Method for adapting influenza viruses to Vero cell |  | Singapore LakeShore |  | the United States, Singapore |  | Granted |  | 2038 |  | Method/Process |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | HK Yisheng |  | China, the European Union |  | Pending |  | N/A |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| PIKA COVID-19 |  | Composition |  | Liaoning Yisheng |  | South Africa, Russia |  | Granted |  | 2042 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| PIKA COVID-19 |  | containing polynucleotide and its application in preventing or treating COVID-19 |  | Liaoning Yisheng |  | China, Hong Kong, the United States, New Zealand, Singapore, |  | Pending |  | N/A |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Adjuvant |  | Methods for preparing complex for enhancing immune response |  | Beijing Yisheng |  | China, Japan, South Korea, the United States |  | Granted |  | 2039 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Complex for enhancing immune response |  | Beijing Yisheng |  | South Africa, India, Russia, Australia, Japan, South Korea, the United States, China |  | Granted |  | 2039 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Anti-infection and anti-tumor mucosal immune preparation |  | Beijing Yisheng |  | the United States |  | Granted |  | 2038 |  | Composition of matter |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Rabies vaccines |  | Method for removing residual DNA from rabies vaccine products by using ultrasound combined with EDTA solutions |  | Beijing Yisheng |  | China |  | Granted |  | 2030 |  | Method/Process |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | Method for removing foreign protein and host DNA from vaccine products |  | Beijing Yisheng |  | China |  | Granted |  | 2029 |  | Method/Process |

|  |  |  |
| --- | --- | --- |
|  | (1) | Although we filed certain patent applications outside China, some of them are still at the unpublished stage. We have uniformly named the legal status of patent applications outside China that were not granted, whether published or not, as “pending.” |

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***Trademarks and domain names***

As of the date of this Annual Report, we own 24 registered trademarks in China. We have two registered domain names, namely liaoningyishengbio.com and lakeshorebio.com.

As our brand name is becoming more recognized in the vaccine market, we are working to maintain, increase and enforce our rights in this trademark portfolio, the protection of which is important to our reputation and branding.

During the three fiscal years ended March 31, 2025 and up to the date of this Annual Report, we have not been involved in any material proceedings in respect of intellectual property right infringement claims against us or initiated by us. However, there are risks that we may be subject to claims that have infringed the intellectual property rights of third parties, and we may not be able to adequately protect our own intellectual property rights. For details, see “Item 3. Key Information—D. Risk Factors—Risks Related to Our Intellectual Property.”

**Manufacturing**

***Manufacturing facilities***

We have been independently manufacturing our clinical stage biologics. As of the date of this Annual Report, we manufacture YSJATM rabies vaccine in Shenyang, China through our own manufacturing facilities. We have not contracted with third parties to manufacture our marketed product.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements governing record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our manufacturing facilities operate under GMP conditions, which are regulatory requirements for the production of pharmaceuticals that will be used in humans.

Our current manufacturing facilities, certified under China 2010 GMP standard, have an annual production capacity of approximately 15 million doses of YSJATM rabies vaccine. In the fiscal year ended March 31, 2025, we manufactured approximately 11.0 million doses of YSJATM rabies vaccine. Since the GMP certified plant started production in February 2020, the utilization has increased gradually and reached approximately 100%, 117% and 87.5%, for the three fiscal years ended March 31, 2023, 2024 and 2025, respectively. The utilization rate is calculated by dividing the raw material input of a given three-month period by the corresponding production capacity during the same period.

We adopted a series of advanced measures and technologies for the current manufacturing facilities to improve our quality control. See “—Quality Management” for details. We implemented new engineering specifications and equipment and machinery for our manufacturing processes. For example, we developed in-house and implemented sterilization technology and devices in the heating, ventilation, air-conditioning and cooling systems used in its manufacturing procedures to ensure product quality and purity for human use. We leveled up our manufacturing techniques to elevate the product standard of our vaccines, such as enhancing the method to remove residual DNA and protein impurities in vaccines. We also installed the continuous mixing solution tank system and pipeline network to transport fluids throughout the plants, which reduces the chances of contamination and pollution. In addition, we installed the circulating steam system to provide enduring, system-wide sterilization.

Furthermore, to avoid human error and contamination risk, we installed a fully automated transportation vehicle system for sample handling and delivery in our filling and packaging workshop.

We have equipped our current manufacturing facilities with engineering specification to produce YSJATM rabies vaccine, which is different from the engineering specification for PIKA-related products. If the demand for YSJATM rabies vaccine were to decrease, we could modify our current manufacturing facilities accordingly and upgrade the engineering specification with bioreactor specification to produce PIKA-related products. Based on our manufacturing experience, we believe the relevant modification process is practicable and manageable and can be completed in a timely manner.

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***Expansion plan***

We own the land use right to three adjacent parcels of land located in Shenyang Economy and Technology Development Zone, Shenyang, China with an aggregate site area of 215,357 sq.m. To facilitate the R&D efforts and the potential product launches, we plan to establish new manufacturing workshops in China to meet additional commercial demand of new product launches. The following table sets forth certain details of our expansion plan.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project** |  | **Construction area** | |  |  | **Actual/expected construction commencement date** |  | **Expected construction completion date** |  | **Expected manufacturing capacity** |
|  |  |  | **(sq.m.)** |  |  |  |  |  |  | **(in total number of doses/year)** |
| Two manufacturing workshops for PIKA rabies vaccine in Shenyang, China |  |  | 11,500 |  |  | March 2021 |  | December 2026 |  | 35 million |

We may face a number of uncertainties in implementing our expansion plan, including our ability to obtain the requisite filings, permits, licenses and approvals for the construction and operation of the new facilities, the risk of construction delays and delays in equipment procurement, and our ability to timely recruit sufficient qualified staff. Furthermore, if we fail to receive the NDA approvals of our product candidates or conduct product launches in a time manner, or at all, we may have the additional manufacturing capacity underutilized, which could adversely impact our prospects, business and liquidity.

***Manufacturing Process***

The following diagram summarizes the major steps of the manufacturing process of YSJATM rabies vaccine.

A diagram of a flowchart

AI-generated content may be incorrect.

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The following is a brief description of the key steps in our manufacturing process.

|  |  |  |
| --- | --- | --- |
|  | ● | *Anabiosising and passaging of Vero cells*. Vero cells used for production are taken out from the working cell bank and restored to normal state through temperature change to meet the needs of culturing. The anabiosised cells are cultured in specific bottles with culture media. After several generations, the cells can be used for subsequent virus infection. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Passaging and inoculation of virus, washing and changing virus culture media, virus harvest*. The virus will reproduce after being inoculated to the cultured Vero cells, and then be used in the later production process. The virus is also key ingredients of vaccine, which can be used as antigen to activate immune system to produce immune response. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Centrifugation, ultrafiltration and concentration*. The virus is separated from the debris of the host cells through the centrifugation process, and the harvested virus solution undergoes ultrafiltration to reach effective antigen concentration. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Inactivation and hydrolyzation of virus.* The nucleic acid structure of the virus is destroyed through the action of the inactivating agent 3-propiolactone, after which the virus loses its ability to infect. However, the protein structure is preserved and immunogenicity is retained. In addition, the inactivator is degraded to compounds through hydrolyzation so that it will not affect human body. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Purification*. Through gel chromatography antigen, pure virus antigen is obtained by removing impurities such as impure protein, host DNA, residual serum and antibiotics produced during the process of pre-production. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Formulation and preparation of semi-finished products.* The purified virus is mixed with stabilizers and excipients for subsequent filling. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Filling and lyophilization.* The semi-finished products are transported to the filling equipment through the pipeline system for automatic filling. After filling, the products are transferred to the freeze-drying machine through the automatic feeding and discharging system for freeze-drying, so as to change the products from liquid state to solid state. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Packaging*. The freeze-dried products were capped, lamp inspected and labeled, and then packaged in different specifications in terms of vials and boxes. |

The production period of YSJATM rabies vaccine is approximately five months, and the shelf life of YSJATM rabies vaccine is approximately 36 months.

***Manufacturing machinery and equipment***

Our manufacturing facilities in Shenyang are equipped with machinery and equipment owned by it, including reactors, purifiers, automated media preparation station and lines, freeze-dryer, filling lines, probs and monitoring system, quality inspection and other equipment for different stages of our manufacturing process. We adopted three-, five- and ten-year depreciation lines for our electronic equipment, transportation and mechanical equipment, respectively. As of the date of this Annual Report, based on our regular inspection and maintenance of our equipment, our machines and equipment are in good working condition. We did not experience any material or prolonged interruptions to our manufacturing process due to machinery or equipment failure in the three fiscal years ended March 31, 2025 and to the date of this Annual Report. We update our manufacturing machinery and equipment based on our evaluation of the effectiveness of its performance.

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**Inventory Management**

Our inventory primarily consists of raw materials, packaging materials, testing reagents, instruments, finished goods, and consumables used for our vaccine development. We procure raw materials and packing materials according to the estimated production time of our products, and as the case may be, generally maintain an inventory level of three to six months for raw materials to meet our vaccine production needs, and as the case may be, generally maintain an inventory level of one to two months for our packaging materials. For imported raw materials, we as the case may be, generally maintain an inventory level of six to 12 months. We target to maintain the inventory level of four to six months of finished products according to the batch issuing cycle of biological products and the estimated customer demand. In particular, we will closely monitor the vaccine bidding information of each province and the status of our applications to better plan our production and control our inventory level. In fiscal year of 2025, our inventory level of finished products has increased significantly to more than 12 months which is consistent with the vaccine industry in China, mainly due to adjustments in industry policies, changes in the market supply-demand dynamics, and the prevalence of excess production capacity. To address the higher finished products inventory level, we have increased our marketing efforts to drive end-customer demand and have adjusted our production batches accordingly to better align with the current sales trends.

We established an inventory management system to monitor each stage of the warehousing process according to the GMP regulations. Our inventory management system records inventory data, such as inventory balance and validity period, and keeps track of inventory levels, enabling us to make adjustments whenever necessary. As part of GMP-compliant facilities, we have a warehouse at our manufacturing facilities, including the inspection waiting areas and post inspection areas. Warehouse personnel are required to complete periodic training and are responsible for the inspection, storage and distribution of inventories. All inventory is separately stored in different areas of the warehouse according to the storage condition requirement, usage and batch number. In order to improve our logistics efficiency of our finished vaccine products, in addition to our centralized warehouse for finished vaccine products in our manufacturing site in Shenyang, we have set up 25 satellite transition warehouses located at different regions across China as of March 31, 2025.

**Quality Management**

We established a comprehensive GMP-compliant quality management system to manage the day-to-day operations at our facilities, with a major emphasis on manufacturing management and finished vaccine product management. Our quality management team is divided into quality assurance and quality control teams. Our quality assurance team is responsible for establishing comprehensive quality policies, ensuring our compliance with global quality guidelines and maintaining all quality-related documentation, as well as validation function. Our quality control team is responsible for quality testing, inspection and review for all our products and raw materials. In addition, we have assembled a validation team for quality inspection and validation in respect of our machinery, facilities and manufacturing processes.

Our comprehensive quality management system is supported by various stringent policies relating to vaccine research, development and manufacturing. For instance, we designed and implemented a series of technical and procedural guidelines relating to the manufacturing of YSJATM rabies vaccine, such as cell and strain preparation, formulation and packaging. We also adopted multiple policies on the management of our laboratories, experiment data and samples. Moreover, our quality management system is designed to ensure compliance with the GMP, pharmacopoeia, labeling requirements and other applicable laws and regulations. Quality issues identified are documented, escalated to and reviewed by senior management. We also conduct a formal risk assessment and justification process in accordance with the standards and procedures under our quality management system and policies.

We enhanced our manufacturing technologies and system with the procurement and upgrades of machinery and equipment, such as the sterile isolator, microplate reader, total organic carbon analyzer and chromatography equipment, and have validated their functionality and ability to generate accurate and effective data. We also established various protocols to analyze and evaluate the standard of our manufacturing and packaging processes.

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We established reliable testing procedures for raw materials, work-in-progress products, and finished products, which include (1) multiple procedures for raw and auxiliary materials, such as Earle’s balanced salt solution microbial limits test, sterility test for human albumin solution, and moisture determination test; (2) multiple procedures for work-in- progress products, such as virus titration of single-harvest virus fluids, protein content determination test, and stock solution sterility test for freeze-dried, Vero cell human rabies vaccines; and (3) multiple procedures for finished products, such as protein residue test for Vero cells, residue determination of gentamicin sulfate, and abnormal toxicity test.

From time to time, we adjust our internal protocols, such as those on manufacturing processes and procedures, testing methods, sterile approaches and operating guidelines, to ensure they meet the requirement of the relevant laws and regulations in a timely manner. For instance, we conducted a comprehensive review of our internal protocols in response to the amended appendix of biological products of the Guidelines on Good Manufacturing Practices (the “2020 Amendments”), pursuant to which we made specific amendments or supplementation to more than 200 internal policies. The amendments cover a wide range of our manufacturing and R&D activities, including the testing methods of certain substances, the management and verification guidelines and quality standards relating to certain ingredients, work-in-progress products and culture media, and the operating guidelines involved in multiple quality examination procedures. In addition, we reviewed the profiles and job responsibilities of the relevant quality management personnel to ensure they have the expertise and qualifications required under the 2020 Amendments. We are also in the process of constructing our manufacturing execution system (“MES”) and laboratory information management system (“LIMS”) to promote real-time information collection and enhance the reliability of the data generated or used in our manufacturing and R&D process. The implementation of MES will allow us to establish a reliable platform that digitizes the manufacturing process and integrates multiple management modules, including such for production data management and quality management. The implementation of LIMS, which comprises both computer hardware and software, will allow us to systematically collect, analyze, report and manage their information in the laboratory. We launched the construction of MES and LIMS in February and April 2021, respectively. We officially integrated MES into our manufacturing process for YSJATM rabies vaccine and to officially adopt LIMS. The aggregate implementation fees for MES and LIMS incurred is approximately RMB7.4 million.

In terms of sterility testing, we adopted the soft-chamber isolators, which effectively guarantee the quality of the testing environment. We require all of our inspection staff to have relevant qualifications and receive systematic training on sterility inspection. They are also required to attend regular trainings on sterility inspection methods organized by the Liaoning Provincial Inspection, Testing and Certification Center and the National Institute for Food and Drug Control.

We require all employees to attend employment training as a prerequisite for employment. The training includes subjects on the GMP standards, primary laws and regulations relating to vaccines and drugs in China, microbiology, biosafety, job responsibilities, operational protocols and managerial procedures. Employees must pass our assessments and obtain the requisite certificate before onboarding. Specifically, our key personnel are required to pass a practice-based test on the respective inspection procedures before they assume their responsibilities.

**Sales and Marketing**

***Sales model***

We operate primarily in the Category II vaccines market in China. Pursuant to the PRC laws and regulations, we must win bids in the public tender process of the province-level CDCs, which give us qualification to access the respective province-level markets. As of March 31, 2025, we obtained qualifications at 30 out of 34 province-level CDCs in China. We are then generally required to make direct sales to, and settle payment with, county-level CDCs, which may then distribute to healthcare providers. We are independent from both province-level and county-level CDCs. In addition, we are responsible for the quality control during transportation until the products are delivered to the county-level CDCs. The entire transportation of vaccines must be in a cold-chain, in which the temperature is usually required to range between 2°C and 8°C.

We usually enter into sales agreements with county-level CDCs from time to time based on their purchase orders, instead of long-term agreements. Pursuant to the sales agreements, we are required to deliver products to county-level CDCs, and they generally have seven days after delivery to dispute any quality issues. The purchase price is determined in the public tender process according to the provisions in the public tender agreements. We typically require payment by wire transfer and allow a credit period of three to four months, consistent with industry practice. We typically do not allow return or exchange of vaccines sold or refund unless our products are defective or are substandard or are damaged during transportation.

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As of the date of this Annual Report, we have a dedicated in-house commercialization team of 44 employees, with an average industry experience of over 13 years such as the sales and marketing of biologics at multinational corporations. Our commercialization team mainly monitors our sales performance and seeks growth opportunities by ensuring our sales relationships with CDCs in their covered regions. They manage and supervise our service providers, conduct market research and analysis, and monitor information about product safety and quality. The remuneration of our commercialization team comprises base salary and performance-based bonuses, which are determined based on a comprehensive matrix of factors such as the number, responsiveness, process management and planning, compliance status and information collection ability of the external service providers engaged by the commercialization team members.

In addition, we expect to expand the commercial potential of YSJATM rabies vaccine into certain Southeast Asian countries, such as Singapore, the Philippines, Vietnam and Malaysia. We intend to seek potential partnership and licensing in those countries to facilitate our commercialization process. We plan to assemble a sales force in collaboration with our local business partners, which will comprise both our internal sales management team and local salespersons with extensive resources and know-hows. We also intend to accelerate our business growth overseas by obtaining additional valuable resources through strategic global collaborations and acquisitions. We currently expect to manufacture our YSJATM rabies vaccine through our Shenyang manufacturing facility in compliance with local laws and regulations, including local GMP requirements.

***Marketing service providers***

In line with industry practice, we engage external service providers to support our sales and marketing efforts among practitioners and execute our sales plan. The extensive network of service providers assists in collecting and providing clinical information of products, including the product quality, safety and adverse event data from the clinical sites, monitoring the shipment and inventory at customer warehouse, managing account payable and payment collection, conducting product training and education programs for practitioner. which greatly strengthens our product presence and loyalty in the marketplace. As of March 31, 2025, we engaged over 178 service providers located at different regions to promote our products in China.

We determine the service items required based on our business needs. We then determine the price for each service item in light of market condition of similar services, and the frequencies and amount of services required in light of the demand of our products. We recognize service fee expenses based on the actual amount of services incurred. The service fees are determined through arm’s length negotiations and based on the fair market price.

***Public tender***

We are required to participate in the public tender process held by province-level CDCs in China and win the bid to make sales into the relevant provinces. In the public tender, bidders are typically required to provide their qualifications, proposed pricing, comparison with actual price in other regions, proposed major business terms, after-sale service plan, their financial credentials and introduction of products. A successful bid typically leads to a one- or two-year qualification to sell products within the relevant provinces. During such qualified period, vaccines must be sold at the bid price accepted during the tender in the relevant region. County-level CDCs can purchase vaccines from any successful bidder.

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***Pricing***

We determine the prices of our marketed product based on a number of factors, including competitive market position, market demands, cost of productions, product quality, affordability, price quotation of competing products in the bidding process, and the specific requirements from province-level CDCs as part of the bidding process. We will also price the product candidates after obtaining NDA approvals in the future, the market price of which will be influenced by a number of factors, such as our costs of production, price quotations of competing products in the bidding process, our technological advantages, product quality and market trends, as well as changes in the levels of supply and demand. In addition, certain province-level CDCs may provide administrative guidance on pricing issues to relevant county-level CDCs under their administrative power, and such guidance may be determined on a stand-alone province level and/or on a case-by-case basis.

***Transportation and storage***

We implement cold-chain transportation and storage in the entire delivery process to the county-level CDCs to ensure real time monitoring and control of temperature, and as well as tracking system to keep records of the temperature of vaccines during transportation and storage. As a result, we adopted cold chain logistics for product delivery primarily by engaging logistic companies with professional capabilities to make transportation of pharmaceuticals to deliver products via ground transportation, during which the temperature of the storage space of our products must be controlled and maintained in accordance with the relevant requirements. In addition, we also engaged 25 satellite transition warehouses located at different regions across China as March 31, 2025, through which we delivered our vaccines to county-level CDCs.

**Customers**

We started the sales of YSJATM rabies vaccine and began to recognize the related revenues from October 2020, pursuant to which our customers are county-level CDCs. As required by government regulations and in line with industry practice, we participate in the public tender process of the province-level CDCs, and if we are successful in our bidding, the relevant province-level CDC will generally provide a public notice, pursuant to which we enter into sales agreements and settle payments directly with county-level CDCs, which then distribute to healthcare providers. See “—Sales and Marketing—Sales Model.”

**Raw Materials and Suppliers**

The principal raw materials required for the production of our biologics involves animal-based cells, plasma albumin, calf serum and Medium 199 powder. We obtain materials largely from suppliers in China and maintain at least two suppliers for all but one of the raw materials we use. We have historically not experienced any shortages in the raw materials we use, and the prices have generally remained stable. However, a risk exists that an interruption in supplies would materially harm our business. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. We typically maintain inventory of raw materials sufficient for three months of production. Recently, in response to adjustments to China-US trade policies and the ongoing escalation of trade tensions, we have implemented strategic procurement of plasma albumin and Medium 199 powder. This initiative, aimed at maintaining a four to six month inventory, aligns with the strategic objective of ensuring the stability of core raw material supplies. In addition, we perform periodical reviews of our suppliers and facilities in accordance with GMP requirements.

Purchases from our top five suppliers accounted for 66.9%. 49.2% and 55.5% of our total purchases in the fiscal years ended March 31, 2023, 2024 and 2025, respectively, and purchases from our largest supplier accounted for 37.9%, 20.2% and 16.6% of our total purchases in the same periods, respectively.

**CROs**

Consistent with industry practice, we engaged certain independent CROs to conduct (1) preclinical efficacy tests, safety evaluation, compatibility studies on packing materials, and tests such as antigen component or structure tests and other chemical and biological tests; and (2) certain clinical trial design and implementation services. We selected CROs based on various factors, including their reputation, research experience, quality and equipment and machinery in the vaccine and pharmaceutical fields. In particular, we have engaged CROs in the R&D of YSJATM, PIKA rabies vaccine, YS-HBV-002 and YS-ON-002.

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Generally, we entered into separate agreements with CROs for each preclinical and services and executed statements of work for each preclinical or clinical trial services. Key terms of such service agreements with CROs are summarized as follows:

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| --- | --- | --- |
|  | ● | *Services*. With respect to preclinical studies, the CROs mainly provide services, including but not limited to: (1) efficacy and safety evaluation, such as acute toxicity test in mice and long-term toxicity test in animals; (2) compatibility studies on our products and their packaging; (3) tests such as antigen component quality or structure tests and other chemical and biological tests. With respect to clinical trials, the CROs provide clinical monitoring and inspection services, clinical research coordinator services, data management services, medical monitoring services, and biological samples management to us. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Term*. The term of agreements for preclinical studies mainly ranges from one to three years. The term of agreements for clinical trials generally expires after the completion of clinical trials. The CROs are generally required to complete the relevant preclinical and clinical services within the prescribed time limit. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Payments*. We are required to make payments to the CROs according to milestones of services and payment terms as defined in the relevant service agreements. Payments are either on lump-sum basis or in installments according to milestones of the respective services. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Confidentiality*. The CROs shall not disclose or disseminate any confidential information without our consent, such as material, data and information provided by us for the contracted services. |

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| --- | --- | --- |
|  | ● | *Dispute resolution*. In the event of any disputes related to the enforcement of any agreement, the parties shall negotiate amicably. If an agreement cannot be reached, the parties have the right to sue. |

|  |  |  |
| --- | --- | --- |
|  | ● | *Intellectual property rights*. Substantially all intellectual property rights arising from the preclinical studies and clinical trials conducted by CROs will be owned by us. In certain cases and as prescribed under the relevant agreements, such as when we develop new technological results with the technological service results provided by certain CROs during the contractual term, the intellectual property rights may belong to both parties. |

**Competition**

Our industry is highly competitive and subject to rapid and significant change. While we believe that our management’s research, development and commercialization experience provide us with competitive advantages, we face competition from biopharmaceutical companies (including specialty pharmaceutical companies), generic drug companies, biologics drug companies, academic institutions, government agencies and research institutions.

For YSJATM rabies vaccine, which is currently marketed in China, we primarily face competition from China-based pharmaceutical companies. For our product candidates, we expect to face competition from a broad range of global and local pharmaceutical companies. Many of our competitors have significantly greater financial, technical and human resources than we have, and mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel immunological biologics or vaccines that are more effective, safer or less costly than our current or future product candidates, or obtain regulatory approval for our products more rapidly than we may obtain approval for our product candidates.

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**Licenses, Permits and Approvals**

As of the date of this Annual Report, we have obtained material licenses, permission or approvals for our current business operations in China, and none of such license, permission or approvals current in effect have been withdrawn or revoked by the competent governmental authorities.

The following table sets out a list of material licenses, permits and approvals currently held by us.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product** |  | **License/Permit** |  | **License/Permit Holder** |  | **Authority** |  | **Validity Period** |
| YSJATM rabies vaccine |  | Drug Re-registration Certificate |  | Liaoning Yisheng |  | Medical Products Administration of Liaoning Province |  | July 13, 2025 - July 12, 2030 |

**Insurance**

We have maintained liability insurance in China and Singapore in compliance with relevant local regulations to cover liability claims that may arise from incidents relating to the clinical trials of our product candidates. We maintain compulsory liability insurance for YSJATM rabies vaccine in China. Our existing insurance coverage may not be sufficient to cover any claim for product liability or damage to our fixed assets. We do not maintain any business interruption insurance.

**Legal Proceedings and Compliance**

We are subject to legal proceedings, investigations and claims arising in the ordinary course of our business from time to time, including, among others, actions with respect to product liability and labor disputes. In the three fiscal years ended March 31, 2025 and up to the date of this Annual Report, other than the legal proceedings pending in the Cayman Islands and China as elaborated below, we have not been involved in any litigation or arbitration proceedings pending that could have a material and adverse effect on our business, financial condition or results of operations.

***Legal proceedings in Cayman Islands***

Since December 2023, the Company has been involved in two legal proceedings in the Cayman Islands against Mr. Yi Zhang, the former chairperson of the Board, and his associates.

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On December 22, 2023, the Grand Court of the Cayman Islands (the “Grand Court”) granted the Company an injunction order against Mr. Zhang, which restrained Mr. Zhang from, among other things, taking any steps to exercise any powers of, or hold himself out to be, chairperson of the Board. That injunction was discharged by the Grand Court on February 6, 2024. On February 16, 2024, the Company obtained another injunction order from the Grand Court which restrained Mr. Zhang and his associates, including Nan Zhang, Yun (Monica) Zhang, Lui Chi Keung and Jing Xian Li from, among other things, holding themselves out to be directors of the Company and from taking any steps to exercise any powers as though they were directors. On April 3, 2024, the Company filed an Amended Statement of Claim with the Grand Court in its proceedings against Mr. Zhang and his associates. The Amended Statement of Claim seeks various forms of declaratory and injunctive relief against the defendants as well as damages. On June 7, 2024, Mr. Zhang filed a Defense with the Grand Court which, among other things, alleges that certain present and former directors of the Company took steps to improperly oust Mr. Zhang from, and to seize control of, the Company and that certain present and former directors of the Company breached their fiduciary duties to the Company (which Mr. Zhang has pleaded will be the subject of separate derivative proceedings) and denies the Company’s entitlement to the relief the Company has claimed in its Amended Statement of Claim. On August 2, 2024, the Company filed and served its Reply by which the Company has, among other things, denied these allegations.

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In October 2024, Mr. Zhang filed a Writ of Summons and Statement of Claim (“Writ”) with the Grand Court against the Company and 13 of its current or former directors and Apex Prospect Limited (“Apex”), seeking, amongst other things, (i) declarations on the validity of certain actions of the Company’s Board taken since Mr. Zhang was removed as chairperson of the Board in December 2023; (ii) orders setting aside the February 2024 issue by the Company of 95,269,762 shares (which was the number of shares prior to the share consolidation, in consistency with the Writ) to Apex and any allotments of any shares issued by the Company pursuant to the share incentive plan approved by the Board in May 2024 or, alternatively, declaring that such share issuance and allotments were done for an improper purpose and in breach of the duties of the directors who approved them; (iii) orders that the Company’s Register of Members be rectified to delete any entries in respect of such share issuance and allotments; (iv) an injunction restraining Apex from exercising any rights attaching to the Company’s shares registered in its name or holding itself out to be a shareholder of the Company; (v) an injunction restraining the Company’s current directors from holding themselves out to be directors of the Company or exercising any powers as directors of the Company; (vi) an injunction restraining the Company and its Board from taking any steps to directly or indirectly allotting any further shares pursuant to the May 2024 share incentive plan or taking any actions which may result in the further dilution of Mr. Zhang’s shareholding and/or which would negatively affect the asset value and/or the share price of the Company; and (vii) damages against the director and former director defendants for unlawful means conspiracy against Mr. Zhang.

On October 31, 2024, Mr. Zhang applied to the Grand Court on an *ex parte* basis for an injunction to restrain the Company from (i) issuing new shares or causing Mr. Zhang’s shareholding to be diluted; and (ii) entering into any transactions or dealings with a value in excess of US$50,000 (other than in the ordinary course of business), each until Mr. Zhang had been given 7 day’s prior notice. On December 13, 2024, the Grand Court refused to hear that application on an *ex parte* basis. Mr. Zhang’s injunction application was heard on an inter partes basis on January 21 and 22, 2025 and dismissed by the Chief Justice of the Grand Court.

The Writ of Summons and Statement of Claim in the proceedings commenced by Mr. Zhang were amended on February 7, 2025 and Mr. Zhang discontinued his claims against 6 of the former director defendants on March 21, 2025. The Company and the remaining 7 director defendants filed their Defences to the Amended Statement of Claim on February 24, 2025 and March 17, 2025 respectively. Mr. Zhang filed his Replies to those Defences on March 31, 2025. On April 15, 2025, Mr. Zhang gave notice that he had changed his Cayman Islands attorneys. Mr. Zhang’s new attorneys later gave the Company notice that, on or before June 6, 2025, he intended to seek leave to further amend the Amended Writ of Summons and Amended Statement of Claim.

As of the date of this Annual Report, the legal proceedings in the two Cayman Islands are still ongoing and no further judgments have been rendered by the Grand Court. The parties have agreed that they will seek to have Cayman Islands proceedings consolidated and/or heard together going forward.

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***Legal proceedings in China***

In May 2024, two entities controlled by Mr. Zhang (each, a “Claimant,” and collectively, the “Claimants”) filed arbitration claims respectively with the Kaifeng Arbitration Commission in China against Liaoning Yisheng. The Claimants sought an aggregate amount of RMB919 million ($128 million) of payment, primarily covering fees for R&D services of RMB198 million ($28 million) and accrued interests, borrowings and other fees of RMB721 million ($101 million) until full payment. The Claimants allege that Liaoning Yisheng owes them fees for research and development services from as early as 2002, and that the parties had entered into debt confirmation and repayment agreements respectively in March 2024, pursuant to which Liaoning Yisheng purportedly agreed to repay the Claimants approximately RMB723 million ($101 million) in the aggregate, including fees for R&D services of RMB198 million ($28 million) and accrued interests, borrowings and other fees of RMB525 million ($73 million) until full payment. Through the two aforementioned arbitration proceedings, the Claimants applied for pre-arbitration preservation of Liaoning Yisheng’s assets, requesting the of funds of up to RMB919 million ($128 million) in Liaoning Yisheng’s bank account (the “Freezing Applications”). Liaoning Yisheng applied to the court assisting the execution of the Freezing Applications to replace the subject assets of the Freezing Applications with its inventory of YSJATM rabies vaccine, certain machinery and equipment and properties, with had an appraisal value of approximately RMB919 milllion ($128 million). In consideration of the potential negative impact from the freezing of the bank accounts on Liaoning Yisheng’s cash flow and business operations, the court granted Liaoning Yisheng’s application.

In May 2024, a Claimant filed arbitration claims with the Kaifeng Arbitration Commission in China against Beijing Yisheng. The Claimant alleged that Beijing Yisheng owed the Claimant certain fees and other amounts since 2021 due to historical reorganization transactions, and that the parties entered into debt confirmation and repayment agreements in March 2024, pursuant to which the Claimant claimed that Beijing Yisheng had agreed to repay the Claimant approximately RMB59 million ($8 million) in the aggregate. The Claimant sought an arbitration award of RMB83 million ($12 million), which included the principal amount and other funds derived therefrom, in payment from Beijing Yisheng.

As of the date of this Annual Report, the Kaifeng Arbitration Commission did not issue awards on these three cases. For the above cases there is uncertainty regarding the timing or ultimate resolution of such matters, and therefore, an estimate for the reasonably possible loss or a range of reasonably possible losses cannot be made.

**Environmental Protection, Occupational Health and Safety, and Social Responsibility**

We are subject to environmental protection and occupational health and safety laws and regulations in China. As of the date of this Annual Report, we have not had any incidents or complaints that would materially and adversely affect our business, financial condition or results of operations. We strive to operate our manufacturing facilities in a manner that protects the environment and the health and safety of our employees and communities. We implemented company-wide environmental, health and safety (“EHS”) policies and operating procedures relating to waste treatment, process safety management, workplace health and safety requirements, and emergency planning and response. For instance, for the waste treatment, we incorporated the waste management and minimization requirement to establish the characterization and management of wastes or by-products which are either disposed or recycled. For the process safety management, we established minimum requirements related to machine safety, trial process safety and personal protection. We also designated responsible personnel to ensure employees’ awareness and compliance with the EHS policy. With respect to our manufacturing process and facilities, we implemented a series of measures to reduce the potential pollution and waste associated with our manufacturing activities. For instance, the biologically active waste liquid discharged in our production process is subject to a high-temperature inactivation process, through which it reaches the relevant discharge standard. In addition, we engage qualified service providers to dispose solid waste generated in our manufacturing process in accordance with the medical waste regulations. We also continuously upgrade our manufacturing techniques and raw materials and consumables to minimize the negative impact of our manufacturing activities on the environment.

We entered into employment contracts with our employees in accordance with the applicable PRC laws and regulations. We hire employees based on their merits, and it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics. We also strive to provide a safe working environment for our employees. We implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. In particular, we established and implemented guidelines in accordance with relevant PRC laws and regulations on the storage, management, handling and use of viruses and bacteria. These guidelines include those related to the recording and inspection of lots of viruses and bacteria, a multi-department approval process to obtain viruses and bacteria from our inventory, as well as the safe disposal of viruses and bacteria. Our employees with specified responsibilities, including handling certain equipment and conducting animal research, are required to hold relevant qualifications, as well as wearing proper safety gear when working. We conduct safety inspections of our manufacturing facilities regularly.

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**Regulations**

***Laws and Regulations in China***

*Laws and Regulations Relating to Drugs*

*Major regulatory authorities*

We conduct our business in PRC and we are now principally subject to the supervision of the National Medical Products Administration and its local counterparts. The National Medical Products Administration was established in accordance with the Institutional Reform Program of the State Council promulgated by the National People’s Congress (the “NPC”) in March 2018, and the predecessor of the National Medical Products Administration is the China Food and Drug Administration (the “CFDA,” together with the National Medical Products Administration, hereinafter collectively, the “NMPA”). The NMPA is the primary regulatory agency for pharmaceutical products and businesses and regulates almost all of the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations), and it is under the supervision of State Administration for Market Regulation (the “SAMR”), a newly established institution for supervising and administrating the market in China.

The Center for Drug Evaluation (the “CDE”), which is a subsidiary of the NMPA, conducts the technical evaluation on each drug and biologic application to assess the safety and efficacy of each candidate. The National Health Commission of the PRC, formerly known by the names the Ministry of Health and National Health and Family Planning Commission (hereinafter collectively, the “NHC”), is China’s primary healthcare regulatory agency. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites. NHC also plays a significant role in drug reimbursement.

The National Institutes for Food and Drug Control is a public institution directly subordinate to CFDA and the statutory authority and supreme technical arbitration institution for inspecting the quality of pharmaceuticals and biological products. It is responsible for the approval and registration inspection, import inspection, supervision and inspection, safety evaluation of drugs, biological products, medical devices, foods, dietary supplements, cosmetics, laboratory animals and package materials and the lot release of biological products, the research, distribution and management of the national drug and medical device reference materials and bacterial and viral strains for production verification, as well as the relevant technical research.

Chinese Center for Disease Control and Prevention is a public welfare institution established by the government to implement the national-level disease control and prevention and the public health technology management and services. Its main responsibility is to enhance the research on the disease control and prevention strategies and measures, participate in the vaccine research, carry out vaccine application result evaluation and immunity planning strategy research, and provide technical guidance and assessment on the implementation of the national immunity strategy under the leadership of NHC and the key tasks in national disease control and prevention.

*Reform of medical and healthcare system*

Pursuant to the Opinions of the State Council on Deepening the Reform of the Medical and Healthcare System issued on March 17, 2009, the reform of the medical and healthcare system has been orderly conducted. The medical insurance system has been gradually improved and the basic medical mechanism has been consolidated and improved.

On October 25, 2016, the State Council introduced the Plan for Healthy China 2030, which proposes to (1) improve the system for collaborative innovation involving different aspects of policy, industry, education, research and practice, and promoting medical innovation, transformation and upgrading, (2) research to establish an examination and approval system based on clinical effects, and raise the examination and approval standards for drugs (medical devices), and (3) accelerate the review and approval of innovative drugs (medical devices) and new drugs (medical devices) that are urgently needed in clinical practice.

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According to the Notice of the Key Tasks of Deepening the Reform of Medical and Healthcare System in the second half of 2020, issued by the General Office of the State Council in July 2020, the government shall improve the public health emergency supplies guarantee system and increase investment in research and development of vaccines, drugs, and rapid testing technologies. Besides, the government shall gradually establish and improve the drug information traceability mechanism, and realize the “one product, one code” of the drugs which are applied to centralized procurement and use by national organizations and vaccines.

In July 2023, six authorities in China, including the National Health Commission, the National Healthcare Security Administration and the National Medical Products Administration, jointly issued the Key Work Tasks for Deepening the Reform of Pharmaceutical and Health System in the Second Half of 2023, confirming the key tasks and work arrangements for further deepening the medical reform, which proposes to carry out comprehensive clinical evaluation of medicines and improve the working mechanism for monitoring the use of medicines. Besides, the PRC government shall carry out full-coverage inspections of vaccine manufacturers and random inspections of blood product manufacturers.

On June 3, 2024, the General Office of the State Council issued the Key Work Tasks for Deepening the Reform of Pharmaceutical and Health System in 2024, which confirms the key tasks and work arrangements for further deepening medical reform and innovation. Pursuant to this document, the government shall optimize medicine utilization and management, deepen the reform of the medicine review and approval system, and enhance the medicine supply guarantee mechanism.

*Drug research and development*

Pursuant to the Drug Administration Law of the PRC (the “Drug Administration Law”), last amended on August 26, 2019 and became effective on December 1, 2019, the State encourages the R&D of new drugs, and protects the legal rights and interests of citizens, legal persons and other organizations in the research and development of new drugs. The dossier on new drug R&D, including the manufacturing method, quality standards, results of pharmacological and toxicological tests and the related data, documents and the samples, shall, in accordance with the regulations of NMPA be submitted to the competent authority for approval before the clinical trial is conducted. The NMPA shall, within 60 business days from the date on which the application for such clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. When a new drug has gone through the clinical trial and passed the evaluation, a drug registration certificate shall be issued upon approval by NMPA.

According to the Provisions for Drug Registration (the “Drug Registration Provisions”) which was last revised on January 22, 2020 and became effective on July 1, 2020, clinical trial of drugs shall be subject to approval, and bioequivalence test shall be filed; clinical trial of drugs shall comply with the Good Clinical Practice of Pharmaceutical Products (the “Good Clinical Practice”) and shall be carried out by drug clinical trial organizations which comply with the relevant provisions. Clinical trials of drugs shall consist of phases I, II, III and IV clinical trials as well as bioequivalence test. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing clinical research. On September 6, 2013, the Announcement of the NMPA on Drug Clinical Trial Information Platform providing that, instead of the aforementioned registration filed with the NMPA, all clinical trials approved by the NMPA and conducted in the PRC shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Information Platform.

The Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs was promulgated by the NMPA on July 24, 2018, according to which, if the applicant does not receive any negative or questioning opinions from the CDE within 60 days after the application is accepted and the fees are paid, the applicant can carry out the clinical trials in accordance with the submitted trial protocol.

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The institutions for non-clinical safety evaluation and study and clinical trial organizations shall respectively implement the Good Laboratory Practice for Non-Clinical Laboratory Studies which became effective on September 1, 2017, and Good Clinical Practice for Clinical Laboratory Studies which was effective on September 1, 2003 and last revised on April 23, 2020 and became effective on July 1, 2020. If certain actions in the preclinical trial research and clinical research conducted for a clinical application trial, and/or in the application procedures for registration of medicines, are in violation of the relevant rules and regulations, the NMPA is authorized to handle such cases pursuant to the Measures regarding Non-compliance with Relevant Rules of Research and Application for Registration of Medicines (Trial) promulgated on and effective from September 1, 1999.

*Regulations on human genetic resources*

The Ministry of Science and Technology promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC in July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. The Ministry of Science and Technology further promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources in October 2017, which became effective in December 2017 and simplified the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

The Regulation on the Management of Human Genetic Resources, as promulgated by the State Council on May 28, 2019, which was last revised on March 10, 2024 and became effective on May 1, 2024, further regulates the collection, preservation, usage and provision of 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 competent health authority of the State Council is responsible for the management of human genetic resources at the national level, and the competent departments for human genetic resources under the provincial governments are responsible for the management of human genetic resources at local level. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources (including organs, tissues, cells and other genetic materials of the human genome and genes) in China or provide human genetic resources abroad.

Pursuant to the Implementation Measures of Administrative Regulations of the PRC on Human Genetic Resources promulgated by the Ministry of Science and Technology on May 26, 2023, which came into effect on July 1, 2023, institutions established or actually controlled by foreign organizations and individuals shall include the following circumstances: (i) the foreign organization or individual holds or indirectly holds 50% or more of the shares, equity, voting rights, property shares, or other similar rights and interests of an institution; (ii) the foreign organization or individual holds or indirectly holds less than 50% of the shares, equity, voting rights, property shares, or other similar rights and interests of the institution, but the voting rights or other rights and interests enjoyed by it or him/her are sufficient to dominate or exert a significant impact on the decision-making, management, and other acts of the institution; (iii) the foreign organization or individual is able to dominate or exert a significant impact on the decision-making, management, and other acts of the institution through investment relations, agreements, or other arrangements; and (iv) any other circumstance prescribed by laws, administrative regulations, and rules.

*Laws and regulations on drug registration*

According to the currently effective Drug Registration Provisions, if all the regulatory requirements are satisfied, the NMPA will grant a new drug certificate valid for five years and the applicant shall apply for renewal six months prior to its expiration date. According to the Drug Registration Provisions, drug registration is regulated according to Chinese medicine, chemical medicine and biological products. The Drug Registration Provisions provides detailed procedural and substantive requirements for the key regulatory concepts established by the Drug Administration Law, confirms a number of reform actions that have been taken in the past years, including (1) the full implementation of Marketing Authorization Holder System and implied approval of the commencement of clinical trial; (2) implementing associated review of drugs, excipients and packaging materials; and (3) introducing four procedures for expedited registration of drugs, which are procedures for ground-breaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval.

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On December 21, 2017, the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations was promulgated by the NMPA and further replaced by the Announcement on the Release of Three Documents including the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) issued by the NMPA on July 7, 2020. The three documents include the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial), Procedures for the Evaluation and Approval of the Listing Application for Conditional Approval of Drugs (Trial) and Procedures for Prioritized Evaluation and Approval for Drug Marketing (Trial), which, among others, allow the applicant to apply for the breakthrough therapy drug procedure during the phase I and II clinical trials and normally no later than the commencement of phase III clinical trials for the innovative or improved drugs, which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over the existing treatments. In addition, when applying for the marketing license of a drug, for the drugs with obvious clinical value, the applicant can apply for the prior evaluation and approval procedure.

According to the Special Examination and Approval of Registration of New Drugs (the “Special Examination and Approval Provisions”) which was promulgated and implemented on January 7, 2009 by the NMPA, the NMPA conducts special examination and approval for new drug registration applications when (1) the effective constituent of drug is extracted from plants, animals and minerals, and the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines, as well as the preparations thereof and the biological product, have not been approved for marketing in China and abroad; (3) the new drugs are for treating the Acquired Immune Deficiency Syndrome, malignant tumors and orphan diseases and have obvious advantages in clinic treatment; or (4) the new drugs are for treating diseases with no effective methods of treatment. The Special Examination and Approval Provisions further provides that the applicant may file for special examination and approval at the clinical trial application stage if the drug candidate falls within items (1) or (2), and if the drug candidates fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

*Laws and regulations on drug manufacturing*

Pursuant to the Drug Administration Law and the Implementing Regulations of the Drug Administration Law of the PRC (the “Drug Administration Implementing Regulations”), a drug manufacturing enterprise is required to obtain a Drug Manufacturing License from the relevant provincial drug administration authority of the PRC. The grant of such permit is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. Pursuant to the Drug Administration Implementing Regulations and the Measures on the Supervision and Administration of the Manufacture of Drugs amended on November 17, 2017 and January 22, 2020 and effective on July 1, 2020 (the “Drug Manufacture Supervision Measures”), the drug manufacturing license is valid for five years and the drug manufacturing enterprises shall apply to the original authority that issued such license for renewal six months prior to its expiration date. Where the marketing authorization holder consents to the production of pharmaceutical preparations, the marketing authorization holder shall apply to the provincial department of the NMPA for a Drug Manufacturing License and subject it to the inspection and other administrative supervision by government agencies.

The Guidelines on Good Manufacturing Practices (the “Guidelines”) which were amended in 1998 and 2010, set the basic standards for the manufacture of pharmaceuticals. The 2010 amendments to the Guidelines were promulgated by the Ministry of Health (now known as the NHC) on January 17, 2011 and came into effect on March 1, 2011. The Guidelines comprise a set of detailed standard guidelines governing the manufacture of drugs, including quality management, organization and personnel, plant and facilities, equipment, materials and products, confirmation and verification, production management, quality control and quality assurance, commissioned production and commissioned inspection, product shipping and recall, and self-inspection. Besides, the major differences between the 2010 revised edition and the 1998 revised edition of the Guidelines include the following: (1) the 2010 revised edition has more emphasis on the aseptic condition and purification during the production process; for example, the exposed processing areas of some non-sterile products shall be designed according to requirements for sterile products; (2) the 2010 revised edition enhances requirements for the production equipment and facilities, which involve not only the design and layout of the production area, storage area, quality control area and auxiliary area, but also the design, installation, maintenance, use, cleaning, status marking and calibration of the equipment and facilities; (3) the 2010 revised edition enhances the standard of management for drug manufacturing enterprises, including but not limited to (i) enhancing the qualification requirements for key personnel, which should at least include the heads of the manufacturer, production management, quality management, and the qualified person; and (ii) requiring manufacturers to establish a quality assurance system with the support of a complete documentation system to ensure its effective operation; and (4) the 2010 revised edition requires proactive or retrospective adoption of quality risk management, which means a systematic process for the assessment, control, communication and review of quality risks, throughout the entire product life cycle.

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The NMPA issued the amended appendix of biological products to the Guidelines on Good Manufacturing Practices (the “2020 Amendments”) in April 2020, which came into effect on July 1, 2020, except for the requirement on information system which came into effect in July 2022. The 2020 Amendments contain 63 articles in eight chapters, with six new added articles and 15 revised articles. The major changes under the 2020 Amendments include the following: (1) the 2020 Amendments require the manufacturers of biological products to establish and improve the biological safety management system in accordance with the laws and regulations related to biological safety management; (2) the 2020 Amendments further enhance the requirements for relevant practitioners, which include the requirements that (i) the training and examination of key personnel shall be strengthened and (ii) the authorized personnel designated to oversee and administer quality control shall hold a bachelor’s degree or above in pharmacy, medicine or other related specialties, and shall have more than five years’ experience in production quality management in related fields; (3) the 2020 Amendments add some detailed provisions concerning the production management and quality management, such as the requirements that (i) the suitability of culture media shall be examined, (ii) the acceptance criteria for chromatographic separation columns and methods for cleaning or sterilizing them shall be specified, and (iii) the adjuvants used for vaccines production shall be consistent with the relevant manufacturing process and quality standards approved by or filed with the drug administration authority; and (4) the 2020 Amendments also mandate that vaccine manufacturers shall truthfully record in electronic means all the data formed in the process of production and inspection to ensure that the whole production process is continuously compliant with the statutory requirements.

According to the Drug Administration Law, the requirement of obtaining a Good Manufacturing Practice Certificate is cancelled and the pharmaceutical manufacturing company shall comply with Good Manufacturing Practice for Drugs, establish and improve upon a drug manufacturing quality management system, ensure the whole drug manufacturing process continuously comply with statutory requirements.

*Administration of affairs concerning laboratory animals*

Pursuant to Regulations for Administration of Affairs Concerning Laboratory Animals approved by the State Council on October 31, 1988 and revised for the third time on March 1, 2017, the Administrative Measures on Good Practice of Laboratory Animals promulgated and implemented on December 11, 1997, and the Administrative Measures on the Certificate for Laboratory Animals (Trial) promulgated on December 5, 2001 and implemented on January 1, 2002, performing experimentation on animals requires a License for Use of Laboratory Animals.

*Pharmaceutical directions and labels of pharmaceutical products*

According to the Measures for the Administration of the Pharmaceutical Directions and Labels of Drugs effective on June 1, 2006, the pharmaceutical directions and labels of drugs should be reviewed and approved by the NMPA. A pharmaceutical direction should include the important scientific data concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug’s common name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug’s name, ingredients, character, specifications, description of the drug’s indications and contraindications, precautions, dosage, date of production, product batch number, valid term, approval number, manufacturing enterprise and any adverse reactions.

*Advertisements of drugs*

On April 29, 2021, the SCNPC revised the Advertising Law of the PRC, according to which certain contents shall not be included in advertisement of drugs, such as an assertion or guarantee on the efficacy or the safety, stating a cure rate or effective rate.

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*Pharmaceutical product export*

According to the Approval by NMPA on Certain Issues of Pharmaceutical Products Export, promulgated and effective on September 20, 1999, whether the enterprise can obtain the right to operate import and export business and the qualification shall be approved by relevant foreign trade authority. The pharmaceutical products export shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the pharmaceutical supervisory and administrative departments support the export in principle based on the national policy of encouraging exports. However, under the Drug Administration Law, the export licenses issued by the relevant NMPA are required for the export of narcotics and psychotropic substances falling within the restricted scope prescribed by the State.

On November 9, 2018, the NMPA promulgated Regulations on the Administration of Certificates of Export Sales of Pharmaceuticals, according to which, where a drug manufacturer applies for a Drug Export Sales Certificate, it shall submit an application form for a drug export sales certificate to the local drug regulatory department at the provincial level. The term of validity of the Drug Export Sales Certificate shall not exceed two years and shall not exceed the term of validity of all the certificates in the application materials, and a new application shall be made before the expiry of the period of validity.

*Drug recalls*

According to the Measures on Drug Recall effective from November 1, 2022, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and making an investigation and evaluation with respect to the drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety or any violation of statutory requirements in respect of any drugs sold in PRC, such manufacturer must start the drug recall procedures. Where a drug is recalled, the drug operating units and users should assist such manufacturer to satisfy its recall obligations by communicating the drug recall information and any feedback, controlling and recovering such drugs according to the recall plan.

*Laws and regulations relating to vaccines*

According to the Vaccine Administration Law of the PRC (the “VAL”), promulgated by the SCNPC on June 29, 2019 and came into effect on December 1, 2019, vaccines are divided into two categories based on whether it is under national immunization programs or not. For vaccines under national immunization programs, the competent health department of the State Council shall, in conjunction with the public finance department of the State Council, among others, organize centralized bidding or unified negotiation, and form and release bid price or transaction price, and vaccines shall be uniformly purchased by all provinces, autonomous regions and municipalities directly under the Central Government. Vaccines under other immunization programs other than vaccines under national immunization programs and vaccines not covered by immunization programs shall be purchased as organized by all provinces, autonomous regions and municipalities directly under the Central Government through provincial public resource trading platforms.

*Vaccine administration*

On January 15, 2017, the General Office of State Council issued Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines, among others, to improve the work mechanism for the management of vaccines and promote the independent R&D and quality improvement of vaccines. The VAL requires the most stringent management system for vaccines, and at the same time, supports the basic research and applied research on vaccines, promotes the development and innovation of vaccines, including the development, production and reserve of vaccines for the prevention and control of serious diseases in the national strategy. Entities and individuals engaged in vaccine development, production, circulation and vaccination shall abide by the laws, regulations, rules, standards and specifications, ensure that the information during the whole process is true, accurate, complete and traceable, assume responsibilities in accordance with the law and accept social supervision.

Vaccine marketing authorization holders shall establish an electronic vaccine traceability system, which is connected with the national electronic vaccine traceability collaboration platform to realize the traceability and verifiability of the smallest packaging units of vaccines in the whole process of production, circulation and vaccination.

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*Development and registration of vaccines*

On October 14, 2005, the NMPA promulgated the Notice on Issuing Six Technical Guidelines including the Technical Guidelines on Preclinical Study of Preventive Vaccines, which specified the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

According to the VAL, clinical trials of vaccines shall be conducted or organized for implementation by Grade III medical institutions that meet the conditions prescribed by the drug administrative department under the State Council and the competent health department under the State Council, or by disease prevention and control institutions at or above the provincial level.

A vaccine to be marketed within the territory of China shall be approved by the drug administrative department under the State Council and obtain a drug registration certificate; when applying for registration of a vaccine, an applicant shall provide true, sufficient and reliable data, information and samples. With respect to the vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the drug administrative department under the State Council shall prioritize their evaluation and approval.

*Production and lot release of vaccines*

Whoever engages in vaccine production activities shall, in addition to meeting the conditions for engaging in drug production activities as prescribed in the Drug Administration Law, also meet the following conditions: (1) having moderate scale and sufficient capacity reserves; (2) having systems, facilities and equipment for ensuring bio-safety; and (3) meeting the needs of disease prevention and control. A vaccine marketing authorization holder shall have the capacity for production of vaccines. If it is really necessary to entrust the production of vaccines in excess of its capacity, the vaccine marketing authorization holder shall obtain the approval of the drug administrative department under the State Council. Where it accepts the entrustment to produce vaccines, it shall abide by the provisions of this Law and the relevant provisions of the State, so as to guarantee the quality of vaccines.

The State has a lot release system for vaccines. Each batch of vaccines shall, before being sold or imported, be examined and inspected according to the relevant technical requirements by the lot release institution designated by the drug administrative department under the State Council. If the requirements are met, a lot release certificate shall be issued; otherwise, a notice on rejecting lot release shall be issued. According to the Measures for Administration of Lot Release of Biological Products (the “Lot Release Administration Measures”) issued on December 13, 2002 and amended on February 1, 2018, the vaccine products with marketing approval shall be subject to document review, onsite verification and sample inspection by the designated drug control institution and pass the biological product lot release approval before the marketing and sales of each batch of products. On December 11, 2020, the SAMR amended the Measures for Administration of Lot Release of Biological Products, which came into effect on March 1, 2021 and does not make material changes on the substance of aforementioned provisions.

On July 8, 2022, the NMPA promulgated the Administrative Provisions on the Manufacture and Circulation of Vaccines, according to which, the marketing authorization holder shall assume the primary responsibilities for the safety, effectiveness and quality controllability of vaccines, carry out the management activities of post-marketing manufacture, circulation and other links of vaccines in accordance with laws and regulations and assume the corresponding responsibilities. An access system is implemented for the manufacture of vaccines and strictly controls the establishment of new vaccine manufacturers. A newly established vaccine manufacturer shall, in addition to meeting the conditions for the establishment of a vaccine manufacturer, conform to the relevant policies of the competent authority of the national vaccine industry. When applying for entrusted manufacture of vaccines, the entrusting party and the entrusted party shall, in accordance with the requirements of the relevant technical guiding principles, carry out research, evaluation and necessary verification, and the entrusting party shall, after completing the alteration of the corresponding production scope of the Drug Manufacturing License, file an application with the Center for Administrative Services and Complaints & Reports of the NMPA.

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*Circulation of vaccines*

Based on the Drug Administration Law and the Law of the PRC on the Prevention and Treatment of Infectious Diseases, the State Council formulated and issued the Regulation on the Administration of Circulation and Vaccination of Vaccines on March 24, 2005 and revised this regulation on April 23, 2016. According to the Regulation on the Administration of Circulation and Vaccination of Vaccines, there are two types of vaccines. Category I vaccines refer to the vaccines provided by the government to citizens free of charge. Category II vaccines refer to other vaccines with which the citizens are voluntarily inoculated at their own expenses. Vaccine manufacturers shall supply Category I vaccines only to the provincial disease prevention and control institutions or other county-level designated disease prevention and control institutions according to the government purchase contract. The Category II vaccines shall be subject to collective purchase organized by provincial disease prevention and control institutions on the provincial public resource trading platform, and purchased by the disease prevention and control institutions and then distributed to local vaccination units. Besides, the vaccine manufacturers shall abide by the rules on the administration of vaccine storage and transport, and guarantee the quality of vaccines. Vaccines shall be stored and transported in the environment with the prescribed temperature during the entire process, shall not be isolated from the cold chain, and the temperature shall be monitored and recorded at regular time.

On June 29, 2019, the SCNPC promulgated the VAL, which involves, among others, the research and development, registration, production, lot release, circulation, vaccination, monitoring and handling of abnormal reactions of the vaccines, as well as the management after the marketing of vaccines.

On March 27, 2020, the Decision of the State Council to Amend and Repeal Certain Administrative Regulations (2020) (the “Decision”) was issued and came into effect on the same day. According to the Decision, certain articles of seven administrative regulations were revised and ten administrative regulations, including the Administration of Circulation and Vaccination of Vaccines, were repealed. The repeal of the Administration of Circulation and Vaccination of Vaccines did not have a significant impact on our production and business activities. Prior to the Decision, the VAL had in effect replaced the Administration of Circulation and Vaccination of Vaccines, since it covers certain key provisions, including the circulation and vaccination of vaccines, monitoring and handling of abnormal reactions, and relevant supporting measures.

According to the Opinions on Further Enhancing Vaccine Circulation and Vaccination Administration issued by the General Office of State Council on January 15, 2017, both the public vaccines and private vaccine should be procured online on the provincial public resource trading platform in accordance with the principles of transparency, competition, and fair trade.

According to the VAL, the competent health department under the State Council shall, in concert with the finance department under the State Council and other departments, organize centralized bidding or unified negotiation to form and publish the bid-winning price or transaction price of vaccines under the National Immunization Program, and all provinces, autonomous regions and municipalities directly under the Central Government shall implement centralized procurement. The procurement of vaccines under other immunization program and vaccines not under the immunization program other than those under the National Immunization Program shall be organized by provinces, autonomous regions and municipalities directly under the Central Government through provincial public resources trading platforms.

The price of vaccines shall be set reasonably and independently by the vaccine marketing authorization holder according to law. The price level, price difference rate and profit rate of vaccines shall be kept within a reasonable range.

A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, supply vaccines to the disease prevention and control institution. The disease prevention and control institutions shall supply vaccines to inoculation entities in accordance with the relevant provisions. Entities or individuals other than the disease prevention and control institutions shall not supply vaccines to inoculation entities, and inoculation entities shall not accept such vaccines. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, deliver vaccines to the disease prevention and control institution or the inoculation entity designated thereby. The vaccine marketing authorization holder and disease prevention and control institution that distribute vaccines themselves shall have the conditions for cold chain storage and transport of vaccines or may entrust eligible vaccine distribution entities to distribute vaccines. Vaccine marketing authorization holders shall establish an electronic vaccine traceability system, which is connected to the national electronic vaccine traceability collaboration platform to realize the traceability and verifiability of the smallest packaging units of vaccines in the whole process of production, circulation and vaccination. The disease prevention and control institutions shall truthfully record the information on vaccine circulation and vaccination in accordance with the relevant provisions, and shall provide the traceability information to the national electronic vaccine traceability collaboration platform in accordance with the relevant provisions.

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A vaccine marketing authorization holder shall, when selling vaccines, provide a copy of the certificate of lot release or an electronic document affixed with its seal. If it sells imported vaccines, it shall also provide a copy of the imported drug clearance form or an electronic document affixed with its seal. A disease prevention and control institution or an inoculation entity shall, when receiving or purchasing vaccines, ask for the abovementioned supporting documents, and preserve them for inspection for at least five years after expiry of validity of the vaccines. A vaccine marketing authorization holder shall, in accordance with the provisions, set up true, accurate and complete sales records, and preserve them for inspection for at least five years after expiry of the validity of the vaccines.

According to the VAL, whoever engages in vaccine production activities shall, in addition to meeting the conditions for engaging in drug production activities as prescribed in the Drug Administration Law, meet the following conditions: (1) having moderate scale and sufficient capacity reserves; (2) having systems, facilities and equipment for ensuring bio-safety; and (3) meeting the needs of disease prevention and control. According to the Government Procurement Law of PRC, vaccine suppliers shall meet the following requirements as a supplier in government procurement: (1) having the capacity to assume civil liabilities independently; (2) having a good business reputation and sound financial and accounting systems; (3) having the equipment and professional expertise needed for performing contracts; (4) having a clean record of paying taxes and making financial contributions to social security funds in accordance with law; (5) having committed no major breaches of law in its business operation in the three years prior to its participation in the procurement; and (6) other requirements provided for in laws and administrative regulations. Other specific requirements may differ slightly from province to province, but generally speaking, vaccine suppliers should possess qualifications required for vaccine manufacturers, including but not limited to the Drug Manufacturing License and the drug registration approval.

*Price Control of Vaccines*

Pursuant to the VAL, vaccine price shall be determined by the vaccine marketing license holder in a legal, independent and rational manner. The price level, spread rate and profit rate of the vaccine shall be maintained at a reasonable level. The inoculation entity shall not charge any fees for the inoculation of vaccines under immunization programs. The inoculation entity that inoculates the vaccine not covered by immunization programs may, in addition to charging the vaccine fee, charge the vaccination service fee. The standards for charging vaccination service fees shall be determined by the competent price department of the people’s government of the province, autonomous region or municipality directly under the Central Government in conjunction with the public finance department.

According to the Administrative Provisions on the Manufacture and Circulation of Vaccines, disease prevention and control institution, vaccination entity and the relevant parties of the entrusted storage and transportation enterprise shall, in accordance with the requirements of the national whole-process electronic traceability system for vaccines, faithfully record the information on the sale, storage, transportation and use of vaccines to realize the whole-process traceability of unit packages from production to use. The vaccine distributor shall, as required by the marketing authorization holder, truthfully and completely record the information on storage and transport.

*Adverse Events*

Pursuant to the VAL, if a lot release agency discovers any major quality risk of a vaccine during the lot release process, it shall promptly report to the drug supervision and administration department of the State Council and the drug supervision and administration departments of the People’s Governments of different provinces, autonomous regions or municipalities directly under central government. The departments receiving the report should immediately conduct an on-site inspection of the marketing authorization holder of the vaccine and notify the lot release agency to not approve or suspend the lot release of the marketing authorization holder’s related or all products based on the inspection results and order the rectification of the marketing authorization holder. In addition, for suspected abnormal reactions to vaccination, the disease prevention and control institutions shall report in a timely manner in accordance with related regulations, organize investigations and diagnoses, and inform the recipients or their guardians of the results of the investigations and diagnoses. If there is a dispute over the results of the investigation or diagnosis, an application for verification can be made in accordance with the verification method formulated by the health authorities under the State Council. In accordance with their respective responsibilities, the health authorities and drug supervision and administration departments of the People’s Governments at or above the districted city level should organize the investigations and handling of any vaccination that causes death or severe disability of the recipient or any suspected abnormal group reactions to vaccination that have a major impact on the society.

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Pursuant to the Lot Release Administration Measures, in any of the following situations, the lot release agencies should report to the drug supervision and administration departments of the provinces, autonomous regions or municipalities directly under central government where the lot release applicants and the production sites locate, suggest on-site inspections, and copy to the NMPA: (1) the sterility test is not qualified; (2) the effectiveness indexes such as efficacy are not qualified in two consecutive lots of inspection; (3) the material review indicates potential serious issues in quality control of the manufacturing, or the deviation in manufacturing techniques, quality difference, or failures and accidents in manufacturing need to be further investigated; (4) the application materials or samples for lot release may have authenticity problems; and (5) other situations that indicate major quality risks of the product. During the investigation and handling of the above-mentioned problems, the approval process or issuance of the corresponding varieties of the lot release applicant may be temporarily suspended. The drug supervision and administration departments of the provinces, autonomous regions, or municipalities directly under central government should conduct an on-site inspection within 10 days after receiving the notifications and recommendations from the lot release agencies. The drug supervision and administration departments of the provinces, autonomous regions, or municipalities directly under central government should provide a technical evaluation and a clear conclusion regarding the quality risks of to the lots of relevant products mentioned by the lot release agencies within 10 days after the inspection. Under extreme circumstances, the departments can appropriately extend the periods mentioned above with reasons provided.

*Animal epidemic prevention*

The Law of the PRC on Animal Epidemic Prevention (the “Animal Epidemic Prevention Law”) issued by the SCNPC on July 3, 1997 and last amended on January 22, 2021, took effect on May 1, 2021. According to the Animal Epidemic Prevention Law, animal epidemics are classified into three categories based on their harm to the breeding industry and human health. Rabies falls under the Category II as it may do serious harm to human and animals and cause major financial losses and social impact. When an animal epidemic of Category II breaks out, the following control measures shall be taken: (1) the administrative department for agriculture and rural area under the local people’s government at or above the county level shall demarcate the epidemic locations, epidemic areas and vulnerable areas; and (2) the local people’s government at or above the county level shall, where necessary, organize the relevant departments and entities to take measures such as isolation, killing, destruction, disinfection, bio-safety treatment, emergency vaccination and restriction on the movement and circulation of the susceptible animals, animal products and related goods. Furthermore, under the Animal Epidemic Prevention Law, the entities and individuals that raise dogs shall have them administered with veterinary rabies vaccines regularly as required by relevant laws and regulations, and register at the local dog registration authority with an immunization certificate issued by an animal clinic.

*Regulations relating to data privacy and anti-bribery*

*Data privacy*

Pursuant to the Notice of the Supreme People’s Court, the Supreme People’s Procuratorate and the MPS on Legally Punishing Criminal Activities Infringing upon the Personal Information of Citizens which was issued in 2013, and the Interpretation of the Supreme People’s Court and the Supreme People’s Procuratorate on Several Issues regarding Legal Application in Criminal Cases Infringing upon the Personal Information of Citizens which was issued on May 8, 2017 and took effect on June 1, 2017, the following activities may constitute the crime of infringing upon a citizen’s personal information: (1) providing a citizen’s personal information to specified persons or releasing a citizen’s personal information online or through other methods in violation of relevant national provisions; (2) providing legitimately collected information relating to a citizen to others without such citizen’s consent (unless the information is processed, not traceable to a specific person and not recoverable); (3) collecting a citizen’s personal information in violation of applicable rules and regulations when performing a duty or providing services; or (4) obtaining a citizen’s personal information by purchasing, accepting or exchanging such information in violation of applicable rules and regulations.

Pursuant to the Notice of the General Office of the State Council on Issuing the Measures for the Management of Scientific Data issued by the General Office of the State Council on March 17, 2018, all entities and individuals shall comply with the relevant national laws and regulations as well as departmental rules in relation to collecting, producing, using and managing scientific data, and shall not carry out activities endangering the national security, social public interests and others’ legitimate rights and interests by using scientific data.

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The PRC Civil Code, which was issued by the NPC on May 28, 2020 and became effective on January 1, 2021, provides that a natural person’s personal information shall be protected by law, and the processing of personal information shall be subject to the principle of legitimacy, rightfulness and necessity, with no excessive processing.

The PRC Data Security Law was promulgated by the SCNPC on June 10, 2021 and became effective on September 1, 2021. The PRC Data Security Law stipulates the measures to support and promote data security and development and establish and optimize the national data security management system, and clarifies organizations’ and individuals’ responsibilities in data security.

The Personal Data Protection Law (the “PDPL”) was issued by SCNPC on August 20, 2021 and took effect on November 1, 2021, stipulates the scope of personal information and the ways of processing personal information, establishes rules for processing personal information and for transfer offshore, and clarifies the individual’s rights and the processor’s obligations in the processing of personal information. The PDPL also strengthens the punishment for those who illegally process personal information.

On July 7, 2022, the Cyberspace Administration of China published Outbound Data Transfer Security Assessment Measures, which became effective on September 1, 2022 and outlined the security assessment process for outbound data transfer.

The Provisions on Promoting and Regulating Cross-border Data Flows, which was promulgated by the CAC and came into effect on March 22, 2024. According to the Provisions on Promoting and Regulating Cross-border Data Flows, to provide data abroad, any data handler shall declare security assessment for providing data abroad to the national cyberspace administration through the cyberspace administration authority at the provincial level at its locality if it satisfies either of the following condition: (i) Where a critical information infrastructure operator provides personal information or important data abroad; or (ii) Where any data processor other than a critical information infrastructure operator provides important data abroad or, as of January 1 of the current year, provides personal information (excluding sensitive personal information) of not less than 1 million people or sensitive personal information of not less than 10,000 people in aggregate to overseas parties. Other regulatory measures like standard contract or personal information protection certification may also apply in outbound data transfer activities.

*Anti-bribery*

According to the Anti-Unfair Competition Law of the PRC (the “Anti-Unfair Competition Law”), passed by the SCNPC on September 2, 1993, became effective on December 1, 1993 and last amended on June 27, 2025 and will come into effect on October 15, 2025, unfair competition refers to that in the course of production and operating activities, the operators disrupt the market competition order and damage the legitimate rights and interests of other operators or consumers in violation of the provisions of the Anti-unfair Competition Law. Pursuant to the Anti-unfair Competition Law, operators shall abide by the principle of voluntariness, equality, impartiality and integrity, and adhere to laws and business ethics during market transactions. Operators in violation of the Anti-unfair Competition Law shall bear corresponding civil, administrative or criminal liabilities depending on the specific circumstances.

Furthermore, pursuant to the Anti-Unfair Competition Law, business operators shall not use money and properties or other means to bribe the following organizations or individuals for the purpose of seeking transaction opportunities or competitive advantage: (1) staff of the counterparty; (2) organizations or individuals entrusted by the counterparty to handle the relevant matters; or (3) organizations or individuals who make use of their authority or influence to influence the transaction. Business operators may explicitly give discount to a counterparty, or pay commission to a middleman in their transactions. In such case, the business operators shall record the discount or commission in its accounts truthfully. Business operators who receive discount or commission shall also record it in their accounts truthfully. Bribery committed by a staff member of a business operator shall be deemed as bribery committed by the business operator, unless the business operator has evidence to prove that the conduct of the staff member is irrelevant to seeking transaction opportunities or competitive advantage for the business operator. Where a business operator violates these provisions and offer bribes or accept bribes, the regulatory authorities shall confiscate its illegal income and impose a fine ranging from RMB100,000 to RMB1,000,000. In cases of severe violation, a fine of RMB 1,000,000 to 5,000,000 shall be levied, and the business licenses may be revoked.

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According to the Interim Provisions on the Prohibition of Commercial Bribery (the “Prohibition Commercial Bribery Provisions”), which was promulgated by the State Administration of Industry and Commerce (currently known as the State Administration for Market Regulation) on November 15, 1996, commercial bribery refers to an act of offering money or property or using other means by an operator to the other entity or individual for the purposes of selling or buying goods, among which “other means” refer to the means used to provide any types of benefits other than money or property, such as offering overseas or domestic travel. According to the Anti-Unfair Competition Law and the Prohibition Commercial Bribery Provisions, regulatory authorities may impose fines depending on the seriousness of the cases and if there is any illegal income, such income shall be confiscated.

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 in March 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies of a province for the first time, its production will not be allowed to be purchased by public medical institutions in this province within the next two years after the relevant list is published.

According to the Criminal Law of the PRC, which was last amended on December 29, 2023 and became effective on March 1, 2024, whoever, for the purpose of seeking illegitimate benefits, gives money or property to a staff member of a company, an enterprise or any other entity, shall be sentenced to imprisonment or criminal detention and shall also be fined, depending on the amount involved. An act of giving money or any property to state functionaries to seek illegitimate benefits shall be considered a crime of offering bribes. Whoever commits the crime of offering bribes shall be sentenced to imprisonment or criminal detention and shall also be fined and subject to confiscation of property, depending on severity of the situation.

*Regulations relating to national medical insurance program*

National Medical Insurance Program The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. Pursuant to the Opinions on the Establishment of the New Rural Cooperative Medical System forwarded by the General Office of the State Council on January 16, 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has spread to the whole nation thereafter. The State Council promulgated the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In 2015, the PRC government announced the Outline for the Planning of the National Medical and Health Service System (2015-2020) which aims to establish a basic medical and health care system that covers both rural and urban citizens by 2020.

*Regulations Relating to Importation and Exportation of Goods*

According to the Administrative Provisions on the Recordation of Customs Declaration Entities of the PRC, promulgated by the General Administration of Customs of the PRC on November 19, 2021 and came into force on January 1, 2022, the consignee, consignor and customs declaration enterprise of import and export goods filed with the customs in accordance with these regulations may handle customs declaration business within the customs territory of the PRC. Consignors and consignees of imported and exported goods shall go through customs declaration entity recordation formalities with the competent customs departments in accordance with the applicable provisions. Consignors and consignors of import and export goods and customs declaration enterprises that apply for recordation shall obtain the qualification of market entities; among which, the consignees and consignors of import and export goods shall also obtain recordation of foreign trade operators if they apply for recordation.

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*Regulations relating to product liability*

Pursuant to the Product Quality Law of the PRC promulgated on February 22, 1993 and latest amended on December 29, 2018 by the SCNPC, the seller shall be responsible for the repair, replacement or return of the product sold if (1) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (2) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (3) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of the purchased product, the seller shall compensate for such losses.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated October on 31, 1993 and amended on August 27, 2009 and October 25, 2013 to protect consumers’ rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendments made on October 25, 2013, all business operators must pay attention to protecting customers’ privacy and must strictly keep confidential any consumer information they obtain during their business operations. In addition, in extreme situations, medical 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.

Pursuant to the PRC Civil Code which was promulgated by the NPC on May 28, 2020 and became effective on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

*Regulations relating to foreign investment*

*Foreign investment*

Investment activities in the PRC by foreign investors were principally governed by the Special Administrative Measures (Negative List) for Access of Foreign Investment (2024 version) (the “Negative List”) and Catalogue of Industries for Encouraging Foreign Investment (2022 version) (the “Encouraging List”). The Negative List, which came into effect on November 1, 2024, sets out special administrative measures in respect of the access of foreign investments in a centralized manner, and the Encouraging List which came into effect on January 1, 2023, sets out the encouraged industries for foreign investment.

*Foreign-invested enterprises*

On December 29, 1993, the SCNPC issued the PRC Company Law (the “Company Law”), which was last amended on December 29, 2023 and came into effect on July 1, 2024. The Company Law regulates the establishment, operation and management of corporate entities in China and classifies companies into limited liability companies and limited companies by shares. According to the Foreign Investment Law of the PRC, which was promulgated by the NPC on March 15, 2019 and came into effect as of January 1, 2020, the state shall implement the management systems of pre-establishment national treatment and negative list for foreign investment, and shall give national treatment to foreign investment beyond the negative list. Simultaneously, Sino-foreign Equity Joint Ventures of the PRC, the Wholly Foreign-owned Enterprises Law of the PRC and Sino-foreign Cooperative Joint Ventures of the PRC were repealed on January 1, 2020.

On December 30, 2019, MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information, which came into effect on January 1, 2020 and replaced the Interim Measures for the Recordation Administration of the Incorporation and Change of Foreign-Invested Enterprises, for carrying out investment activities directly or indirectly in PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

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*Regulations relating to environmental protection and fire preventions*

*Environment protection*

The Environmental Protection Law of the PRC (the “Environmental Protection Law”), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

*Environmental impact appraisal*

According to the Administration Rules on Environmental Protection of Construction Projects, which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction.

According to the Environmental Impact Appraisal Law of PRC (the “Environmental Impact Appraisal Law”), promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

*Fire prevention design and acceptance*

The Fire Prevention Law of the PRC (the “Fire Prevention Law”), was adopted on April 29, 1998 and last amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

*Regulations relating to employment, social securities and production safety*

*Employment*

The major PRC laws and regulations that govern employment relationship are the Labor Law of the PRC (the “Labor Law”) (issued by the SCNPC on July 5, 1994, came into effect on January 1, 1995 and revised on August 27, 2009 and December 29, 2018), the Labor Contract Law of the PRC or the Labor Contract Law (promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012 and became effective on July 1, 2013) and the Implementation Rules of the Labor Contract Law of the PRC (the “Implementation Rules of the Labor Contract Law”) (issued by the State Council on September 18, 2008 and came into effect on the same day). According to the aforementioned laws and regulations, labor relationships between employers and employees must be established in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees.

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*Social securities*

According to the Social Insurance Law of PRC, which was issued by the SCNPC on October 28, 2010, came into effect on July 1, 2011 and revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, occupational injury insurance, medical insurance and other welfare plans. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (issued by the State Council on January 22, 1999 and came into effect on the same day and was revised on March 24, 2019) prescribes the details concerning the social securities.

*Housing provident fund*

According to the Regulation Concerning the Administration of Housing Provident Fund, implemented on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center and seal up the employee’s housing accumulation fund account in the bank mentioned above within 30 days from termination of the employment relationship.

*Production safety*

Pursuant to the Production Safety Law of the PRC, which was amended by the SCNPC on June 10, 2021 and came into effect on September 1, 2021, an enterprise shall (1) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (2) establish a comprehensive production safety accountability system and production safety rules, (3) develop production safety standards to ensure production safety and (4) establish safety risk classification management and control system, and take corresponding control measures according to the safety risk classification. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities. The person-in-charge of an enterprise shall be fully responsible for the safety of production of the enterprise.

*Regulations relating to intellectual properties*

*Patents*

According to the Patent Law of the PRC (promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and came into effect on June 1, 2021) and the Implementing Rules of the Patent Law of the PRC (which was promulgated by the China Patent Bureau Council on January 19, 1985, last amended on December 11, 2023 by the State Council and came into effect on January 20, 2024), the term “invention-creations” refers to inventions, utility models and designs. The duration of a patent right for inventions, utility models and designs shall be 20 years, 10 years and 15 years, respectively, commencing from the filing date.

*Trademarks*

Pursuant to the Trademark Law of the PRC (promulgated on August 23, 1982, amended on April 23, 2019 and came into effect on November 1, 2019), and the Implementation Regulations of the Trademark Law of PRC (which was issued on August 3, 2002 and amended on April 29, 2014), the Trademark Office under the China National Intellectual Property Administration (the “Trademark Office”) shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for an additional ten-year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a “first-to-file” principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right of others, nor may any person register in advance a trademark that has already been used by another party and has already gained a “sufficient degree of reputation” through such party’s use. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licenser shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith.

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*Domain names*

In accordance with the Measures for the Administration of Internet Domain Names which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Information Industry is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register.” A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

*Regulations relating to foreign exchange and overseas investment*

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document.

On November 19, 2012, the State Administration of Foreign Exchange (“SAFE”) issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (the “SAFE Circular 59”), which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment in February 2015, which was partially abolished in December 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment, which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020) and was revised on December 4, 2023. The notice cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors’ security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

According to the Notice on Further Optimizing the Cross-border RMB Policy and Supporting the Stabilization of Foreign Trade and Foreign Investment, which was issued by the People’s Bank of China, the NDRC, MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the China Banking and Insurance Regulatory Commission and SAFE on December 31, 2020 and came into effect on February 4, 2021, the RMB income from the capital account of domestic institutions could be used within the business scope approved by the relevant state departments when the following requirements are met: (1) it shall not be used directly or indirectly for expenditures outside the business scope of the enterprise or the expenditures prohibited by national laws and regulations; (2) unless expressly provided otherwise, it shall not be used directly or indirectly for securities investment; (3) unless expressly permitted in the business scope, it shall not be used for giving out loans to the non-associated enterprises; and (4) it shall not be used for constructing or purchasing the real estate for non-self-use (except for real estate development enterprises). In addition, the non-investment oriented foreign investment enterprises could make domestic reinvestment with RMB capital in accordance with the law, provided they comply with current regulations and the domestic investment projects are true and compliant.

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*Regulations relating to M&A*

According to the M&A Rules, which was jointly issued by MOFCOM, the State Assets Supervision and Administration Commission of State Council, SAT, the SAMR, the CSRC, and SAFE, on August 8, 2006 and amended by MOFCOM on June 22, 2009, among other things, (1) the purchase of an equity interest or subscription to the increase in the registered capital of non-foreign-invested enterprises, (2) the establishment of foreign-invested enterprises to purchase and operate the assets of non-foreign-invested enterprises, or (3) the purchase of the assets of nonforeign-invested enterprises and the use of such assets to establish foreign-invested enterprises to operate such assets, in each case, by foreign investors shall be subject to the M&A Rules. Particularly, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an oversea company established or controlled by such domestic company, enterprise or natural person.

*Regulations relating to overseas listing*

On February 17, 2023, the CSRC issued the Trial Administrative Measures for Overseas Listing (“TAMOL”) and five supporting guidelines, which came into effect on March 31, 2023.

The TAMOL provide that an overseas listing or offering is explicitly prohibited under any of the following circumstances: (1) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules of the PRC; (2) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (3) the domestic company, its controlling shareholder(s) or the actual controller have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (4) the domestic company is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (5) there are material ownership disputes over equity held by the controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

According to the TAMOL, a filing-based regulatory regime is adopted to regulate both direct and indirect overseas securities offering and listing by the domestic companies. Direct overseas offering and listing by domestic companies refers to such overseas offering and listing by a joint-stock company incorporated domestically, while the indirect overseas offering and listing by domestic companies refers to the offering and listing by a company in the name of an overseas incorporated entity the major business operations of which are located domestically and such offering and listing is based on the underlying equity, assets, earnings or other similar rights of a domestic company. The TAMOL also provide the criteria of indirect overseas offering and listing by domestic companies which shall be regulated. If the issuer meets both the following criteria, it will be deemed as indirect overseas offering and listing by domestic companies: (1) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (2) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or domiciled in mainland China.

According to the TAMOL, subsequent securities offering of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within 3 working days after the offering is completed. Subsequent securities offering and listing of an issuer in other overseas markets shall be filed as initial public offering, under which filing application with the CSRC shall be submitted within 3 working days after the application documents for offering and listing are submitted overseas. A domestic company that seeks to directly or indirectly list its domestic assets in overseas markets through single or multiple acquisitions, share swaps, transfers of shares or other means, shall fulfil the filing procedure as an initial public offering. Where overseas application documents are not required, the filing shall be made within 3 working days after the first public disclosure of the specifics of the transaction is made by the listed company.

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*Regulations relating to taxation*

*Enterprise income tax*

The Enterprise Income Tax Law of the PRC (the “EIT Law”), promulgated by the NPC on March 16, 2007, effective on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (the “Implementation Rules”), promulgated by the State Council on December 6, 2007, effective on January 1, 2008, last amended on December 6, 2024 and became effective on January 20, 2025 are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC, and non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites, and non-resident enterprises that have not set up institutions or sites in the PRC or that have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

*Value-added tax*

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (issued on December 13, 1993 by the State Council, effective on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017), as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (issued on December 25, 1993 by the Ministry of Finance of the PRC (the “MOF”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011), any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of Value-Added Tax (the “VAT”) and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the SAT issued the Notice on Adjusting VAT Rates on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%. Moreover, according to the Announcement of the SAT on the VAT Issues Concerning the Sale of Biological Products by Drug Trading Enterprises issued on May 28, 2012, if a drug trading enterprise which is a general taxpayer for VAT sells biological products, it could choose a simple method to calculate the VAT to pay based on the sales of biological products and a collection rate of 3%. Additionally, on December 25, 2024, the SCNPC issued the Law of the PRC on Value-added Tax, which will come into effect on January 1, 2026. Simultaneously, the Interim Regulations on Value-added Tax of the PRC will be repealed.

***Laws and regulations in Singapore***

*Laws and regulations relating to clinical trials*

In Singapore, the Health Sciences Authority (“HSA”), a statutory board of the Ministry of Health of Singapore, regulates the conduct of clinical trials of therapeutic products and medicinal products under the Health Products Act (Chapter 122D) and Medicines Act (Chapter 176) and their subsidiary legislations (including Health Products (Clinical Trials) Regulations (“HPCTR”) and the Medicines (Clinical Trials) Regulations 2016 (“MCTR,” together with the HPCTR, collectively, the “Regulations”)), respectively. Certain types of clinical research such as observational clinical trials of therapeutic products and medicinal products and clinical trials on medical devices are not regulated by HSA.

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The Regulations provide that every clinical trial must have one and only one sponsor. However, HSA may, in its discretion, allow more than one sponsor for a clinical trial. A “sponsor” is defined under the Regulations as a person who takes responsibility for the initiation, management or financing of a clinical trial. Under the Regulations, the sponsor of a clinical trial is required, among others:

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|  | (1) | in the case of clinical trial of medicinal products, to apply for and obtain a clinical trial certificate for each principal investigator of the clinical trial before the commencement of the trial; |

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|  | (2) | in the case of clinical trial of medicinal products, to apply for and obtain authorization by HSA for the clinical trial or notify HSA of the clinical trial and receipt of HSA’s acceptance of the notification before the commencement of the trial; |

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|  | (3) | not to make substantial amendments to the trial except with approval of HSA; |

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|  | (4) | to notify HSA of the trial status, suspension, termination and conclusion, and submit final report regarding the trial status within stipulated timelines under respective Regulations; |

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|  | (5) | to ensure that information in the investigator’s brochure for the trial is concise, objective and kept up to date; |

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|  | (6) | to ensure the clinical trial is conducted under supervision of qualified private investigator; |

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|  | (7) | to ensure the clinical trial is only conducted at the specified trial site; |

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|  | (8) | to carry out functions of the sponsor in accordance with principles of good clinical practice (“GCP”) set out in the First Schedule of the respective Regulations; |

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|  | (9) | to put and keep in place arrangements to ensure compliance with principles of GCP; |

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|  | (10) | to notify HSA of serious breaches and urgent safety measures taken to protect subjects against immediate hazard within stipulated timelines under the respective Regulations; |

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|  | (11) | to keep record of clinical trials; |

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|  | (12) | to ensure that all investigational and auxiliary medicinal product used in the trial are labelled in accordance with the labelling requirements set out in Second Schedule of the respective Regulations; and |

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|  | (13) | to report unexpected serious adverse drug reactions to HSA within the stipulated timelines under the respective Regulations. |

The sponsor may delegate all or any of the sponsor’s functions under the Regulations to any person, but any such arrangement does not affect the responsibility of the sponsor.

HSA has power under the Regulations to suspend or terminate a clinical trial, or any part of a clinical trial if it has reasonable grounds to suspect that (a) any information provided in respect of any application for a clinical trial certificate for the trial is false or misleading; (b) any sponsor, principal investigator or person assisting the principal investigator has contravened, is contravening or is likely to contravene any condition to which any clinical trial certificate issued for the trial is subject or any provision of the Regulations; (c) any ground for the conduct of the trial on the basis of scientific validity is no longer applicable or true or (d) the continuance of the trial will compromise the safety of any subject of the trial. In such event, the sponsor and a principal investigator must ensure that the suspension or termination is adhered to by all persons involved in the trial.

A person who is guilty of an offence under MCTR shall be liable on conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding two years or to both.

A person who is guilty of an offence under HPCTR shall be liable on conviction to a fine not exceeding $10,000 or $20,000 depending on the offence or to imprisonment for a term not exceeding six or 12 months depending on the offence or to both.

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*Laws and regulations relating to clinical research material*

The manufacture, import and supply of therapeutic products and medicinal products used as a clinical research material in clinical trials in Singapore is governed by the Health Products Act (Chapter 122D), Medicines Act (Chapter 176) and their subsidiary legislations (including Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (“HPTPCRMR”), Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016 (“MMPCRMR”, together with the HPTPCRMR, collectively, the “CRM Regulations”)), respectively.

The Health Products Act (Chapter 122D) and Medicines Act (Chapter 176) provides that no person shall import, manufacture, assemble or sell (by way of wholesale dealing) any health product or medicinal product without a valid license (product license, import license, manufacturer’s license or wholesale dealer’s license where applicable) and that health products must also not be supplied without product registration. Under the CRM Regulations, certain health product or medicinal products (including among others, those that are manufactured, assembled, imported or supplied as clinical research materials) are exempted from the above licensing requirements, subject to the importer or manufacturer (as the case may be) of clinical research materials giving notice of the import or supply (as the case may be) (“CRM Notification”) to HSA before importing or supplying (as the case may be) the clinical research materials in accordance with the requirements of the CRM Regulations.

According to the clinical trial guidance on clinical research materials published by HSA on 2 May 2017, sponsor of clinical trials (that are regulated by HSA and for which imported or locally manufactured clinical research material is to be used) should submit the CRM Notification on behalf of the importer or local manufacturer to HSA at the time of initial application for clinical trial certificate or authorization or notification (as the case may be) or where such information is unavailable at the time of application, by way of amendment to the application. Before the CRM Regulations came into force, clinical trial material import permits were issued to clinical trial sponsors to facilitate importation of medicinal products for use in the approved drug trials.

Under the CRM Regulations, the sponsor is required to ensure that clinical research materials are only used in accordance with the research protocol, and where the research requires the approval of an institutional review board (“IRB”), only after approval has been obtained from IRB. Unless otherwise allowed by HSA, the sponsor is also required to ensure that any unused clinical research material obtained for the research is disposed of or exported within six months of the conclusion or termination of the clinical research. The sponsor must keep records relating to all clinical research materials that are put to some other use, disposed of or exported for the prescribed period and produce the records for inspection when required by HSA and report unexpected serious adverse drug reactions to HSA within the stipulated timelines.

The import of clinical research materials comprising controlled drugs and psychotropic substances, poisons or radiopharmaceuticals into Singapore is subject to additional licensing requirements.

A person who is guilty of an offence under MMPCRMR shall be liable on conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding two years or to both.

A person who is guilty of an offence under HPTPCRMR shall be liable on conviction to a fine not exceeding $10,000 or $20,000 depending on the offence or to imprisonment for a term not exceeding six or 12 months depending on the offence or to both.

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*Laws and regulations relating to confidentiality of personal data collected and used in clinical trials*

As stated in the First Schedule (principles of good clinical practice) of the Health Products (Clinical Trials) Regulations (“HPCTR”) and the Medicines (Clinical Trials) Regulations 2016 (“MCTR”, together with the HPCTR, collectively, the “Regulations”), the confidentiality of records that could identify clinical trial subjects must be protected, respecting the privacy and confidentiality rules in accordance with any applicable written law or rule or principle of law.

The Personal Data Protection Act 2012 establishes the Singapore regime for the protection of personal data (i.e., data, whether true or not, about an individual who can be identified from that data or other information accessible to the relevant organization) and seeks to ensure that organizations comply with a baseline standard of protection for personal data of individuals.

The nine data protection obligations are summarized as follows:

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|  | (1) | purpose limitation obligation—personal data must be collected, used or disclosed only for purposes that a reasonable person would consider appropriate in the circumstances, and if applicable, have been notified to the individual concerned; |

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|  | (2) | notification obligation—individuals must be notified of the purposes for the collection, use or disclosure of their personal data, prior to such collection, use or disclosure; |

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|  | (3) | consent obligation—the consent of individuals must be obtained for any collection, use or disclosure of their personal data, unless exceptions apply. Additionally, an organization must allow the withdrawal of consent which has been given or is deemed to have been given; |

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|  | (4) | access and correction obligations—when requested by an individual and unless exceptions apply, an organization must: (i) provide that individual with access to his personal data in the possession or under the control of the organization and information about the ways in which his personal data may have been used or disclosed during the past year; and/or (ii) correct an error or omission in his personal data that is in the possession or under the control of the organization; |

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|  | (5) | accuracy obligation—an organization must make reasonable efforts to ensure that personal data collected by or on its behalf is accurate and complete if such data is likely to be used to make a decision affecting the individual or if such data will be disclosed to another organization; and |

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|  | (6) | protection obligation—an organization must implement reasonable security arrangements for the protection of personal data in its possession or under its control; |

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|  | (7) | retention limitation obligation—an organization must not keep personal data for longer than it is necessary to fulfil: (i) the purposes for which it was collected; or (ii) a legal or business purpose; |

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|  | (8) | transfer limitation obligation—personal data must not be transferred out of Singapore except in accordance with the requirements prescribed under the PDPA; and |

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|  | (9) | openness obligation—an organization must implement the necessary policies and procedures in order to meet the obligations under the PDPA and shall make information about its policies and procedures publicly available. |

Non-compliance may lead to financial penalties, civil liability or criminal liability. The Singapore regulator, the Personal Data Protection Commission, also has broad powers to order the organizations to comply with the provisions of the PDPA.

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|  | **C.** | **Organizational Structure** |

The following diagram illustrates our corporate structure as of the date of this Annual Report.

A diagram of a diagram

AI-generated content may be incorrect.

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|  | **D.** | **Property, Plant and Equipment** |

***Owned properties***

As of March 31, 2025, we owned and operated one facility in Shenyang, China primarily for manufacturing. We built two manufacturing workshops for YSJATM rabies vaccine, which are located in the Shenyang Economy and Technology Development Zone, Shenyang, China. We purchased the land use right to this area, which consists of land use rights to three pieces of land adjacent to each other, including (1) a right of land use for 44,655 square meters, which expires in January 2060, (2) a right of land use for 73,724 square meters, which expires in January 2060, and (3) a right of land use for 96,978 square meters, which expires in December 2056.

***Leased properties***

As of March 31, 2025, we operated our business through two leased properties in Beijing and Philippines. Such properties primarily serve as office space. The expiration dates of leased properties in Beijing and Philippines are September 2025 and April 2026, respectively. We plan to renew the leases or negotiate new terms when the existing leases expire.

As of March 31, 2025, our leased property in Beijing with a total gross floor area of 1,533 square meters was subject to a mortgage that had been placed before we entered into the relevant lease agreement. We faced the risks that we may not be able to continue to use the leased property upon foreclosure.

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**ITEM 4A. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of our results of operations and financial condition. This discussion and analysis should be read together with our financial statements and notes thereto included elsewhere in this report. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth under “Risk Factors” and elsewhere in this report.*

|  |  |  |
| --- | --- | --- |
|  | **A.** | **Operating Results** |

**Overview**

We are a global biopharmaceutical company dedicated to discovering, developing, manufacturing and commercializing new generations of vaccines and therapeutic biologics for infectious diseases and cancer.

We commercialize vaccines with revenue and growth potential. We take pride in our marketed vaccine product, YSJATM rabies vaccine, which was the first aluminum-free lyophilized rabies vaccine launched in China. As of the date of this report, approximately 1.1 million doses of YSJATM rabies vaccine were administered for post-exposure protection against rabies. With our track record of commercialization, YSJATM rabies vaccine were achieved high production scalability and wide market recognition. Since we commenced the sales of YSJATM rabies vaccine in October 2020 and to March 31, 2025, we sold more than 35.3 million doses to 1,911 county-level CDCs in China.

In addition to the commercialized YSJATM rabies vaccine, we also have a pipeline of vaccine candidates powered by our proprietary PIKA immunomodulating technology platform. Our proprietary PIKA immunomodulating technology platform is core to the discovery and development of innovative biologics and will continue to be instrumental to our success. As of the date of this report, we have a portfolio of seven innovative product candidates: (1) five product candidates under various clinical development stages, including simplified four-dose regimen for YSJATM (two subsequent sessions included, Zagreb Regimen (2-1-1) & Modified Essen Regimen (1-1-1-1)), PIKA rabies vaccine, PIKA YS-ON-001, PIKA YS-HBV-001 and PIKA YS-HBV-002, and (2) two preclinical stage product candidates, targeting influenza, and cancer, and we believe each has substantial market demand. In addition, we are working on a series of therapeutic targets and products at the discovery stage. We were granted about 46 patents across more than 14 countries and regions relating to our PIKA immunomodulating technology and prophylactic and therapeutic product innovations. We believe that our PIKA immunomodulating technology platform has the potential to nurture a wide variety of innovative vaccines and therapeutic biologics.

As of March 31, 2025, we had an accumulated deficit of $335.4 million. We have funded our operations primarily with proceeds from revenues generated from the sales of our marketed product, YSJATM rabies vaccine and borrowings under our loan facilities.

**Key Factors Affecting Results of Operations**

If the vaccine industry in China does not grow as expected or declines, the results of operations could be materially and adversely affected. If our marketed product and product candidates as well as the related manufacturing, storage, testing, delivery and other procedures do not meet the required quality standards, our business could be harmed, and our revenue and profitability could be materially and adversely affected.

Preclinical or clinical trials involve a lengthy and expensive process with uncertain outcomes. We may not be able to achieve the projected development goal of our product candidates in a timely manner or at all, which may materially and adversely affect our business, financial condition, results of operations and prospects.

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The biopharmaceutical industry is highly regulated. The relevant regulations and policies are complex and regional and subject to changes from time to time. Our ability to obtain and maintain these regulatory approvals is uncertain. Any changes in government regulations and policies may place additional burdens on our business and have a material adverse effect on our financial condition and results of operations.

The increasing number of new approval for domestic human rabies vaccines could intensify the market competition. If the domestic human rabies vaccine market were to contract or the competition were to further intensify, our market share and competitiveness could be adversely affected, which may lead to negative impact on our financial performance and business operation.

***Our ability to increase the sales of our marketed product***

We commenced production of our marketed product, YSJA™ rabies vaccine with our GMP-compliant manufacturing facilities in February 2020 and sales and marketing in October 2020. Since October 2020 and to March 31, 2025, we sold approximately 35.3 million doses of product to 1,911 county-level CDCs in China. The sales volume of our marketed product is expected to have a significant impact on our results of operations. Our ability to increase the sales of our marketed product depends, in part, on whether we are able to effectively implement our marketing strategies. We intend to drive the full-scale commercialization of YSJA™ rabies vaccine to capture the demand for rabies vaccine in China and Southeast Asia. We plan to enhance our sales efforts by expanding our commercialization team, marketing service providers and county-level CDC coverage as well as terminal channel coverage in hospitals and clinics to drive further demand.

***Our ability to commercialize our product candidates***

Our business and results of operations will be dependent on the receipt of regulatory approval for and successful commercialization of our product candidates. Leveraging our proprietary PIKA immunomodulating technology platform, we have developed a robust pipeline of product candidates targeting viral infections and cancer, including five clinical stage candidates and two preclinical candidates. We expect PIKA immunomodulating technology platform to lead and expedite our progress in the development of existing pipeline products. We believe that our accumulated experience and resources in vaccine sales, manufacture and commercialization will lay a solid foundation for our product pipeline development and future expansion. For our other pipeline candidates, we plan to strategically accelerate our development and commercialization based on our PIKA immunomodulating technology to realize our full potential in other important prophylactic and therapeutic areas.

***Our ability to optimize our cost structure***

Our results of operations are affected by our costs and expenses. During the three fiscal years ended March 31, 2025, our results of operations were affected by our R&D, administrative, selling and other expenses. We expect that costs of sales and selling expenses will have a significant impact on our results of operations in the future as we started to sell YSJA™ rabies vaccine in October 2020. We also expect that our selling and marketing related expenses, R&D expenses, and administrative expenses among others, will continue to have a significant impact on our financial performance.

We began the sales and marketing of our marketed product in October 2020. With a pipeline of product candidates from preclinical to late-stage in clinical development, we plan to use our in-house sales and marketing team and external service providers to expand the sales network. In 2024, the rabies vaccine industry saw a significant increase in competition, with the number of rabies vaccine providers rising from eight in 2020 to 12 in 2024. Many of our competitors have significantly greater financial resources, which could affect our ability to compete effectively and gain market share. Due to this competitive environment, we anticipate increased selling expenses to support the effective implementation of the sales plan and maintain a competitive position.

R&D activities are central to our business model. The development of our product candidates requires significant investment of resources over a prolonged period of time. We devoted significant resources to R&D activities. For the fiscal years ended March 31, 2025, 2024 and 2023, our R&D expenses were RMB146.4 million ($20.4 million), RMB302.8 million and RMB318.7 million, respectively. Our current R&D activities primarily relate to the clinical advancement of our product candidates. We will prioritize the advancement of vaccine and protein therapeutic candidates within the infectious disease space, focusing on those with significant market potential and favorable competitive dynamics, and which are synergistic with our existing capabilities and marketing channels. We expect our R&D expenses to continue to increase for the foreseeable future as we progress our product candidates, either from preclinical trials to clinical trials, or further into more advanced stages of clinical trials, and as we continue to support the clinical trials of our product candidates as treatments for additional indications.

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Our administrative expenses primarily included employee benefits expenses primarily relating to salaries, share-based payment and other welfare for our administrative employees, depreciation and amortization and professional service fees. We expect that our administrative expenses will increase as we expand our operations to support our growing business.

We expect our cost structure to evolve as we continue to develop and expand our business. As we continue to invest in expanding our existing product revenue and advancing our R&D initiatives to introduce additional product candidates into clinical trials and ultimately commercialization, we expect to incur additional costs in relation to raw materials procurement, manufacturing, sales and marketing, among other things. We also anticipate increasing legal, compliance, accounting, insurance, and investor and public relations expenses associated with being a public company.

***Our ability to maintain adequate funding for our operations***

We have funded our operations primarily through private equity and debt financing. Going forward, in the event of a successful commercialization of one or more of our product candidates, we expect to fund our operations in part with revenue generated from sales of our marketed products. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Any fluctuation in the funding for our operations will impact our cash flow plan and results of operations.

**Components of Results of Operations**

***Revenue***

We primarily generate revenue from the sales of YSJA™ rabies vaccine. We typically recognize revenue when our customers accept the rabies vaccine products, upon which we have fulfilled our associated performance obligation.

***Cost of revenue***

Our costs primarily consist of material, direct labor and production overheads. Depreciation of property, plant and equipment attributable to manufacturing activities and license amortization are capitalized as part of inventory and expensed as cost of revenue when the product is sold. We anticipate our direct costs associated with the rabies vaccine will increase over time mainly because the price of direct raw materials is expected to rise over time.

***Operating expenses***

*Selling and Marketing Expenses*

Selling and marketing expenses primarily consist of employee benefits, travel and entertainment, promotion and marketing service fees, and other marketing expenses. Employee benefits expenses primarily included salaries, share-based payment and other welfare for our commercialization staff. Traveling and entertainment expenses primarily are incurred by our commercialization staff in their sales activities. Promotion and marketing service fees primarily represented the costs we incurred to engage marketing service providers for the commercialization of YSJA™ rabies vaccines.

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*General and administrative expenses*

General and administrative expenses primarily consisted of employee benefits, depreciation and amortization, provision for trade receivables and inventories, professional service fees and other expense. Employee benefits expenses primarily included salaries, share-based payment and other welfare for our administrative staff. Depreciation and amortization primarily consisted of depreciation for property, plant and equipment and right-of-use assets and amortization for intangible assets used for administrative purposes.

*Research and development expenses*

R&D expenses primarily consisted of employee benefits, testing and clinical trial, consulting service fees, depreciation and amortization, office and leasing and other expenses. Employee benefits expenses primarily included salaries, share-based payment and other welfare for our R&D employees. Testing and clinical trial expenses primarily represented costs we incurred in conducting clinical trials for its product candidates, including in-house testing fees, purchase of raw materials and consumables, and engagement of clinical trial sites and principal investigators. Consulting service fees primarily represented third-party contracting costs with respect to the engagement of CROs and CRCs, and testing and processing services fees charged by such third parties. Depreciation and amortization primarily consisted of depreciation expenses for property, plant and equipment and amortization expenses for intangible assets used for R&D purposes.

*Income tax expense*

We are subject to profit tax on an entity basis on profits arising in or sourced from the jurisdictions where our members are domiciled and operate.

*Cayman Islands.* Under the current laws of the Cayman Islands, LakeShore Biopharma is not subject to tax on income or capital gains. In addition, upon payments of dividends by LakeShore Biopharma to our shareholders, no Cayman Islands withholding tax is imposed.

*Hong Kong.* Under the Hong Kong tax laws, HK Yisheng is exempted from profit tax on its foreign- sourced income and there are no withholding taxes in Hong Kong on remittance of dividends.

*Singapore.* The subsidiary incorporated in Singapore files separate income tax returns in Singapore at Singapore statutory income tax rate of 17%.

*China.* Under the Enterprise Income Tax (“EIT”) Law of the PRC, domestic enterprises and Foreign Investment Enterprises (the “FIE”) are usually subject to a unified 25% EIT rate while preferential tax rates, tax holidays, and even tax exemption may be granted on case-by-case basis. The PRC tax authorities grant preferential tax treatment to High and New Technology Enterprises (“HNTEs”). Under this preferential tax treatment, HNTEs are entitled to an income tax of 15%, subject to a requirement that they re-apply for HNTE status every three years. Since Liaoning Yisheng was approved as an HNTE in November 2024 , Liaoning Yisheng is entitled to a reduced income tax of 15% and is able to enjoy the reduced income tax rate in the next three years. Since Beijing Yisheng was approved as an HNTE in December 2022, Beijing Yisheng is entitled to a reduced income tax rate of 15% and is able to enjoy the reduced income tax rate in the next three years.

*Philippines.* The subsidiary incorporated in Philippines is subject to income tax at 20%.

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**Results of Operations**

The following table summarizes the results of our operations for the period as indicated and provides information regarding the percentage increase or decrease during such periods. This information should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report. The operating results in any period are not necessarily of the results that may be expected for any future period.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2023** | | | | | |  |  | **2024** | | | | | |  |  | **2025** | | | | | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **US$** | |  |  | **%** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| **Revenues** |  |  | 687,201,070 |  |  |  | 100.0 |  |  |  | 573,418,256 |  |  |  | 100.0 |  |  |  | 614,961,584 |  |  |  | 85,670,723 |  |  |  | 100.0 |  |
| Cost of revenues |  |  | 153,360,262 |  |  |  | 22.3 |  |  |  | 117,688,301 |  |  |  | 20.5 |  |  |  | 107,772,147 |  |  |  | 15,013,812 |  |  |  | 17.5 |  |
| **Gross profit** |  |  | **533,840,808** |  |  |  | **77.7** |  |  |  | **455,729,955** |  |  |  | **79.5** |  |  |  | **507,189,437** |  |  |  | **70,656,911** |  |  |  | **82.5** |  |
| **Operating expenses:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Selling and marketing |  |  | 272,927,356 |  |  |  | 39.7 |  |  |  | 301,259,528 |  |  |  | 52.5 |  |  |  | 281,429,426 |  |  |  | 39,206,128 |  |  |  | 45.8 |  |
| General and administrative |  |  | 72,939,790 |  |  |  | 10.6 |  |  |  | 140,086,062 |  |  |  | 24.4 |  |  |  | 128,967,761 |  |  |  | 17,966,588 |  |  |  | 21.0 |  |
| Impairment loss on inventory, property, plant and equipment and other assets |  |  | 8,655,487 |  |  |  | 1.3 |  |  |  | 157,415,875 |  |  |  | 27.5 |  |  |  | 36,715,041 |  |  |  | 5,114,798 |  |  |  | 6.0 |  |
| Research and development |  |  | 318,700,526 |  |  |  | 46.4 |  |  |  | 302,800,992 |  |  |  | 52.8 |  |  |  | 146,369,093 |  |  |  | 20,390,779 |  |  |  | 23.8 |  |
| **Total operating expenses** |  |  | **673,223,159** |  |  |  | **98.0** |  |  |  | **901,562,457** |  |  |  | **157.2** |  |  |  | **593,481,321** |  |  |  | **82,678,293** |  |  |  | **96.6** |  |
| **Loss from operations** |  |  | **(139,382,351** | **)** |  |  | **(20.3** | **)** |  |  | **(445,832,502** | **)** |  |  | **(77.7** | **)** |  |  | **(86,291,884** | **)** |  |  | **(12,021,382** | **)** |  |  | **(14.1** | **)** |
| **Other income (expenses):** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Late fee for income tax: |  |  | (3,603 | ) |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Late fees for social security insurance |  |  | (747,609 | ) |  |  | (0.1 | ) |  |  | (756,201 | ) |  |  | (0.1 | ) |  |  | (454,863 | ) |  |  | (63,367 | ) |  |  | (0.10 | ) |
| Government grants |  |  | 26,072,517 |  |  |  | 3.8 |  |  |  | 20,708,778 |  |  |  | 3.6 |  |  |  | 5,125,566 |  |  |  | 714,046 |  |  |  | 0.80 |  |
| Financial expenses |  |  | (30,857,673 | ) |  |  | (4.5 | ) |  |  | (44,344,808 | ) |  |  | (7.7 | ) |  |  | (15,739,410 | ) |  |  | (2,192,668 | ) |  |  | (2.60 | ) |
| Fair value changes of warrant liability |  |  | 21,358 |  |  |  | - |  |  |  | 4,458,844 |  |  |  | 0.8 |  |  |  | 1,149,792 |  |  |  | 160,178 |  |  |  | 0.20 |  |
| Other income |  |  | 551,760 |  |  |  | 0.1 |  |  |  | 10,572,411 |  |  |  | 1.8 |  |  |  | (4,718,525 | ) |  |  | (657,341 | ) |  |  | (0.80 | ) |
| **Total other expense** |  |  | **(4,963,250** | **)** |  |  | **(0.7** | **)** |  |  | **(9,360,976** | **)** |  |  | **(1.6** | **)** |  |  | **(14,637,440** | **)** |  |  | **(2,039,152** | **)** |  |  | **(2.40** | **)** |
| **Loss before income taxes** |  |  | **(144,345,601** | **)** |  |  | **(21.0** | **)** |  |  | **(455,193,478** | **)** |  |  | **(79.3** | **)** |  |  | **(100,929,324** | **)** |  |  | **(14,060,534** | **)** |  |  | **(16.5** | **)** |
| **Income tax benefit (expense)** |  |  | **(1,133,504** | **)** |  |  | **(0.2** | **)** |  |  | **21,728,607** |  |  |  | **3.8** |  |  |  | **946,873** |  |  |  | **131,910** |  |  |  | **0.20** |  |
| **Net Loss** |  |  | **(145,479,105** | **)** |  |  | **(21.2** | **)** |  |  | **(433,464,871** | **)** |  |  | **(75.5** | **)** |  |  | **(99,982,451** | **)** |  |  | **(13,928,624** | **)** |  |  | **(16.30** | **)** |

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**Fiscal year ended March 31, 2025 compared to fiscal year ended March 31, 2024**

***Revenue***

Our revenue increased by 7.2% from RMB573.4 million for the fiscal year ended March 31, 2024 to RMB615.0 million ($85.7 million) for the fiscal year ended March 31, 2025. This growth was primarily driven by the steady recovery of the domestic economy following the conclusion of the COVID-19 emergency, which facilitated a faster production and operational pace compared to the same period last year. Despite a slight contraction in market size and heightened competition in 2024, which was largely due to the implementation of certain PRC regulations on procedures for managing rabies exposure, we generated a revenue increase of approximately 7% in the fiscal year ended March 31, 2025 from the prior fiscal year. In terms of sales volume, we delivered 7.8 million doses of our products during the fiscal year ended March 31, 2025, representing an approximate 5.28% increase compared to the prior year period. Furthermore, the unit price per dose rose by RMB1.4 due to enhanced market recognition, which contributed to the overall growth in revenue.

***Cost of revenue***

Our cost of revenue primarily consisted of raw material costs, staff costs, manufacturing costs and depreciation expenses. During the fiscal year ended March 31, 2025, we continued to enhance our cost management practices. The cost decreased by 8.4% from RMB117.7 million for the fiscal year ended March 31, 2024 to RMB107.8 million ($15.0 million) for the fiscal year ended March 31, 2025. The decrease was primarily attributable to the following factors: (1) the normalization of production and streamlined operations, which has resulted in higher capacity utilization rates and consequently lower unit fixed costs; and (2) a decrease in the prices of key raw materials, mainly driven by the expansion of procurement channels and changes in market supply and demand dynamics.

***Gross profit and profit margin***

Our gross profit rose by 11.3% from RMB455.7 million for the fiscal year ended March 31, 2024 to RMB507.2 million ($70.7 million) for the fiscal year ended March 31, 2025. This growth was primarily driven by an increase in sales volume. Our profit margin increased from 79.5% for the fiscal year ended March 31, 2024 to 82.5% for the fiscal year ended March 31, 2025. The improvement in gross profit margin was mainly attributable to (1) higher unit prices resulting from strengthened market recognition, and (2) the expansion of raw material procurement channels coupled with, an increase in production batches, which collectively led to lower per-unit costs.

***Selling and marketing expenses***

Selling and marketing (“S&M”) expenses decreased by 6.6% from RMB301.3 million for the fiscal year ended March 31, 2024 to RMB281.4 million ($39.2 million) for the fiscal year ended March 31, 2025, mainly due to the following reasons: (1) during fiscal year 2024, sales momentum slowed in certain periods due to the lasting impact from the COVID-19 pandemic, and we increased our investment in market promotion during the period to better align with future marketing initiatives, further consolidate our market position and enhance our brand recognition, which led to relatively higher S&M expenses; and (2) given that an increasing number of enterprises have obtained market approval for human rabies vaccines in China, market competition has intensified, and we enhanced the intensity and frequency of our marketing efforts in the fiscal year of 2024.

The following table sets forth a breakdown of our S&M expenses in amount and as a percentage of the total selling and marketing expenses for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2025** | | | | | |  |  | **2024** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Promoting and marketing service fees |  |  | 251,299,501 |  |  |  | 89.3 |  |  |  | 275,761,994 |  |  |  | 91.5 |  |  |  | (24,462,493 | ) |  |  | (8.9 | ) |
| Employee benefits |  |  | 26,686,826 |  |  |  | 9.5 |  |  |  | 20,814,258 |  |  |  | 6.9 |  |  |  | 5,872,568 |  |  |  | 28.2 |  |
| Other |  |  | 3,443,099 |  |  |  | 1.2 |  |  |  | 4,683,276 |  |  |  | 1.6 |  |  |  | (1,240,177 | ) |  |  | (26.5 | ) |
| **Total** |  |  | **281,429,426** |  |  |  | **100.0** |  |  |  | **301,259,528** |  |  |  | **100.0** |  |  |  | **(19,830,102** | **)** |  |  | **(6.6** | **)** |

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***General and administrative expenses***

General and administrative (“G&A”) expenses decreased by 7.9% from RMB140.1 million for the fiscal year ended March 31, 2024 to RMB129.0 million ($18.0 million) for the fiscal year ended March 31, 2025, primarily attributable to our ongoing enhancement of cost control framework, achieved through the systematic implementation of cost-saving and efficiency-enhancing initiatives, which helped to effectively lower our overall G&A expenses. These initiatives include the optimization of management processes, stringent control over non-core expenditures, and improved resource utilization.

The following table sets forth a breakdown of our G&A expenses in amount and as a percentage of the total general and administrative expenses for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2025** | | | | | |  |  | **2024** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Employee benefits |  |  | 60,890,979 |  |  |  | 47.2 |  |  |  | 76,935,771 |  |  |  | 54.9 |  |  |  | (16,044,792 | ) |  |  | (20.9 | ) |
| Professional service fees |  |  | 29,650,085 |  |  |  | 23.0 |  |  |  | 35,798,987 |  |  |  | 25.6 |  |  |  | (6,148,902 | ) |  |  | (17.2 | ) |
| Depreciation and Amortization |  |  | 10,555,608 |  |  |  | 8.2 |  |  |  | 6,463,248 |  |  |  | 4.6 |  |  |  | 4,092,360 |  |  |  | 63.3 |  |
| Taxes and surcharges |  |  | 9,106,850 |  |  |  | 7.1 |  |  |  | 6,789,028 |  |  |  | 4.8 |  |  |  | 2,317,822 |  |  |  | 34.1 |  |
| Scrapped inventory |  |  | 6,203,913 |  |  |  | 4.8 |  |  |  | - |  |  |  | - |  |  |  | 6,203,913 |  |  |  | 100.0 |  |
| Office expenses |  |  | 1,174,566 |  |  |  | 0.9 |  |  |  | 1,900,626 |  |  |  | 1.4 |  |  |  | (726,060 | ) |  |  | (38.2 | ) |
| Other |  |  | 11,385,760 |  |  |  | 8.8 |  |  |  | 12,198,402 |  |  |  | 8.7 |  |  |  | (812,642 | ) |  |  | (6.7 | ) |
| **Total** |  |  | **128,967,761** |  |  |  | **100.0** |  |  |  | **140,086,062** |  |  |  | **100.0** |  |  |  | **(11,118,301** | **)** |  |  | **(7.9** | **)** |

***Impairment loss on inventory, property, plant and equipment and other assets***

Our impairment loss on inventory, property, plant and equipment and other assets decreased by 76.7% from RMB157.4 million for the fiscal year ended March 31, 2024 to RMB36.7 million ($5.1 million) for the fiscal year ended March 31, 2025. The decrease in impairment loss on inventory, property, plant and equipment and other assets was primarily attributable to (1) impairment loss on inventory decreased by RMB69.7 million primarily due to impairment charges in connection with COVID-19-related disruptions to our manufacturing operations and production, as well as impairment on raw materials used in our R&D of COVID-19 vaccines, whose impact lessened in fiscal year 2025; (2) impairment loss on property, plant and equipment (“PP&E”) decreased by RMB62.4million, which was attributed to write-down of PP&E related to COVID equipment that was recognized in fiscal year 2024; and (3) impairment loss on intangible assets increased by RMB10.4 million ($1.4 million) primarily related to a long-held patent.

The following table sets forth a breakdown of impairment loss on inventory, PP&E, and other assets, presented in absolute amounts and as a percentage of total impairment loss for the indicated periods.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2025** | | | | | |  |  | **2024** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Impairment loss on other assets |  |  | 8,529,179 |  |  |  | 23.2 |  |  |  | 7,507,036 |  |  |  | 4.8 |  |  |  | 1,022,143 |  |  |  | 13.6 |  |
| Impairment loss on inventory |  |  | - |  |  |  | - |  |  |  | 69,671,843 |  |  |  | 44.3 |  |  |  | (69,671,843 | ) |  |  | (100.0 | ) |
| Impairment loss on property, plant and equipment |  |  | 17,801,862 |  |  |  | 48.4 |  |  |  | 80,236,996 |  |  |  | 50.9 |  |  |  | (62,435,134 | ) |  |  | (77.8 | ) |
| Impairment loss on intangible assets |  |  | 10,384,000 |  |  |  | 28.4 |  |  |  | - |  |  |  | - |  |  |  | 10,384,000 |  |  |  | - |  |
| **Total** |  |  | **36,715,041** |  |  |  | 100.0 |  |  |  | **157,415,875** |  |  |  | **100.0** |  |  |  | **(120,700,834** | **)** |  |  | **(76.7** | **)** |

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***Other income (expenses)***

Our other expenses increased from RMB9.4 million for the fiscal year ended March 31, 2024 to RMB14.6 million ($2.0 million) for the fiscal year ended March 31, 2025, primarily attributable to (1) a decrease of RMB15.6 million in government grants; (2) a decrease of RMB28.6 million in net financial expenses due to the repayment of R-Bridge Loan in fiscal year 2024; and (3) an increase of RMB 15.3 million in other expenses mainly due to disposal of property, plant and equipment.

***Income tax expense***

Our PRC subsidiaries are subject to income taxes in China on their taxable income calculated at a tax rate in accordance with the relevant income tax laws and regulations. We determine deferred taxes for each tax-paying entity in each tax jurisdiction. The potential tax benefits arising from the losses incurred by the subsidiaries have been recorded in our financial statements. Our income tax benefit decreased from RMB21.7 million in the fiscal year ended March 31, 2024 to RMB0.9 million ($0.1 million) in the fiscal year ended March 31, 2025, primarily due to the completion of inventory disposal in fiscal year 2025. The reversal of deferred income tax assets recognized in prior years resulted in an increase in the income tax expense in fiscal year 2025, partially offset by the increase in deferred tax assets arising from impairments of PP&E and other non-current assets.

We evaluate our valuation allowances requirements at each reporting period by reviewing all available evidence, both positive and negative, and considering whether, based on the weight of that evidence, a valuation allowance is needed. When a change in circumstances causes a change in management’s judgment about the ability to realize deferred tax assets, the impact of the change on the valuation allowance is generally reflected in income from operations. The future realization of the tax benefit of an existing deductible temporary difference ultimately depends on the existence of sufficient taxable income of the appropriate character within the carry forward period available under applicable tax law.

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***Net loss***

As a result of the foregoing, we recognized net loss of RMB100.0 million ($13.9 million) and RMB433.5 million for the fiscal years ended March 31, 2025 and 2024, respectively.

***Research and development expenses***

Our R&D expenses decreased by 51.7% from RMB302.8 million for the fiscal year ended March 31, 2024 to RMB146.4 million ($20.4 million) for the fiscal year ended March 31, 2025. The decrease in R&D expenses was primarily attributable to the following reasons as our R&D projects progress through distinct development stages: (1) with the market contraction for COVID-19 vaccines resulting from the end of the COVID-19 pandemic, we decided to terminate our project to commercialize of COVID-19 vaccines, which resulted in a notable decrease in testing and clinical trial expenses related to the COVID-19 vaccine in the fiscal year of 2025; (2) our R&D expenses for the PIKA rabies vaccine decreased by 45% compared to the previous year, which was primarily attributed to the advancement of the clinical trial and the completion of the majority of clinical follow-up visits in earlier phases, resulting in decreased related expenses for clinical trials as the work shifted to the less costly data analysis; and (3) our R&D expenses for the YS-HBV vaccine also experienced an approximately 54% decrease, primarily driven by our decision to terminate the PIKA YS-HBV-002 program following reassessment of its competitive landscape and commercial feasibility; partially offset by the YSJA™ simplified four-dose method regimen Phase III clinical trial was initiated in December 2024, resulting in new R&D expenditure of approximately RMB24.1 million.

The following table sets forth a breakdown of our R&D expenses in amount and as a percentage of total R&D expenses for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2025** | | | | | |  |  | **2024** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Testing and clinical trial fees |  |  | 93,591,766 |  |  |  | 63.9 |  |  |  | 210,997,087 |  |  |  | 69.7 |  |  |  | (117,405,321 | ) |  |  | (55.6 | ) |
| Employee benefits |  |  | 33,137,982 |  |  |  | 22.6 |  |  |  | 56,716,238 |  |  |  | 18.7 |  |  |  | (23,578,256 | ) |  |  | (41.6 | ) |
| Depreciation and amortization |  |  | 13,286,205 |  |  |  | 9.1 |  |  |  | 20,749,231 |  |  |  | 6.9 |  |  |  | (7,463,026 | ) |  |  | (36.0 | ) |
| Office and leasing |  |  | 874,132 |  |  |  | 0.6 |  |  |  | 1,190,874 |  |  |  | 0.4 |  |  |  | (316,742 | ) |  |  | (26.6 | ) |
| Consulting service fees |  |  | 178,741 |  |  |  | 0.1 |  |  |  | 9,058,949 |  |  |  | 3.0 |  |  |  | (8,880,208 | ) |  |  | (98.0 | ) |
| Other |  |  | 5,300,267 |  |  |  | 3.7 |  |  |  | 4,088,613 |  |  |  | 1.4 |  |  |  | 1,211,654 |  |  |  | 29.6 |  |
| **Total** |  |  | 146,369,093 |  |  |  | 100.0 |  |  |  | 302,800,992 |  |  |  | 100.0 |  |  |  | (156,431,899 | ) |  |  | (51.7 | ) |

The following table below sets forth a breakdown of our key R&D projects.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2025** | | | | | |  |  | **2024** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| PIKA Recombinant COVID-19 vaccine |  |  | 4,352,843 |  |  |  | 3.0 |  |  |  | 90,305,820 |  |  |  | 29.8 |  |  |  | (85,952,977 | ) |  |  | (95.2 | ) |
| PIKA rabies vaccine |  |  | 71,501,257 |  |  |  | 48.8 |  |  |  | 128,995,501 |  |  |  | 42.6 |  |  |  | (57,494,244 | ) |  |  | (44.6 | ) |
| PIKA YS-ON-001 |  |  | 1,728,946 |  |  |  | 1.2 |  |  |  | 7,237,524 |  |  |  | 2.4 |  |  |  | (5,508,578 | ) |  |  | (76.1 | ) |
| PIKA HBV vaccines |  |  | 19,510,656 |  |  |  | 13.3 |  |  |  | 42,233,799 |  |  |  | 13.9 |  |  |  | (22,723,143 | ) |  |  | (53.8 | ) |
| PIKA adjuvant |  |  | 5,424,231 |  |  |  | 3.7 |  |  |  | 8,237,970 |  |  |  | 2.7 |  |  |  | (2,813,739 | ) |  |  | (34.2 | ) |
| YSJATM rabies vaccine |  |  | 42,373,898 |  |  |  | 29.0 |  |  |  | 21,293,796 |  |  |  | 7.0 |  |  |  | 21,080,102 |  |  |  | 99.0 |  |
| Other |  |  | 1,477,262 |  |  |  | 1.0 |  |  |  | 4,496,582 |  |  |  | 1.5 |  |  |  | (3,019,320 | ) |  |  | (67.1 | ) |
| **Total** |  |  | **146,369,093** |  |  |  | **100.0** |  |  |  | **302,800,992** |  |  |  | **100.0** |  |  |  | **(156,431,899** | **)** |  |  | **(51.7** | **)** |

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**Fiscal year ended March 31, 2024 compared to fiscal year ended March 31, 2023**

***Revenue***

Our revenue decreased by 16.6% from RMB687.2 million for the fiscal year ended March 31, 2023 to RMB573.4 million ($80.8 million) for the fiscal year ended March 31, 2024, primarily due to COVID-related disruptions affecting our manufacturing operations, and production, which reduced batch approvals and doses available for sale; offset by increases in product price by RMB2.9 per dose due to increased market recognition. The increase in production batches led to an increase in raw materials consumption, while sales volume and revenue decreased due to the decrease in batch approvals which resulting in a decrease in doses available for sale. LakeShore Biopharma sold 7.4 million doses of product for the fiscal year ended March 31, 2024, compared to 9.3 million doses of product for the fiscal year ended March 31, 2023.

***Cost of revenue***

Our cost of revenue primarily consisted of raw material costs, staff costs, manufacturing costs and depreciation expenses. The cost decreased by 23.3% from RMB153.4 million for the fiscal year ended March 31, 2023 to RMB117.7 million ($16.6 million) for the fiscal year ended March 31, 2024. The decrease in costs was attributable primarily to (1) the decrease in sales volume of YSJATM rabies vaccine products due to COVID-related disruptions affecting our manufacturing operations and production, which reduced batch approvals and doses available for sale; and (2) the decrease in unit cost caused by decrease in delivery cost by changing delivery party and increase in production batches.

***Gross profit and profit margin***

Our gross profit decreased by 14.6% from RMB533.8 million for the fiscal year ended March 31, 2023 to RMB455.7 million ($64.2 million) for the fiscal year ended March 31, 2024. The decrease in gross profit was due to the decrease in revenue. Our profit margin increased from 77.7% for the fiscal year ended March 31, 2023 to 79.5% for the fiscal year ended March 31, 2024. The improvement in our profit margin was primarily due to the increase in unit price resulting from increased market recognition and decrease in unit cost caused by decrease in delivery cost by changing delivery party and increase in production batches.

***Selling and marketing expenses***

Selling and marketing (“S&M”) expenses increased by 10.4% from RMB272.9 million for the fiscal year ended March 31, 2023 to RMB301.3 million ($42.5 million) for the fiscal year ended March 31, 2024. The increase in S&M expenses was primarily due to the increase in promoting and marketing service fees, RMB26.4 million, to promote the YSJATM rabies vaccine products continuously and to deal with fierce industry competition.

The following table sets forth a breakdown of our selling expenses in amount and as a percentage of the total selling expenses for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2024** | | | | | |  |  | **2023** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Promoting and marketing service fees |  |  | 275,761,994 |  |  |  | 91.5 |  |  |  | 249,347,280 |  |  |  | 91.4 |  |  |  | 26,414,714 |  |  |  | 10.6 |  |
| Employee benefits |  |  | 20,814,258 |  |  |  | 6.9 |  |  |  | 21,369,530 |  |  |  | 7.8 |  |  |  | (555,272 | ) |  |  | (2.6 | ) |
| Other |  |  | 4,683,276 |  |  |  | 1.6 |  |  |  | 2,210,546 |  |  |  | 0.8 |  |  |  | 2,472,730 |  |  |  | 111.9 |  |
| **Total** |  |  | **301,259,528** |  |  |  | **100.0** |  |  |  | **272,927,356** |  |  |  | **100.0** |  |  |  | **28,332,172** |  |  |  | **10.4** |  |

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***General and administrative expenses***

General and administrative expenses increased by 92.1% from RMB72.9 million for the fiscal year ended March 31, 2023 to RMB140.1 million ($19.7million) for the fiscal year ended March 31, 2024, primarily because (i) the professional service fee increased by RMB34.5 million, mainly including legal fee, auditing fee and D&O insurance; (ii) employee benefits increased by RMB35.6 million.

The following table sets forth a breakdown of our general and administrative expenses in amount and as a percentage of the total general and administrative expense for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2024** | | | | | |  |  | **2023** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Employee benefits |  |  | 76,935,771 |  |  |  | 54.9 |  |  |  | 41,381,933 |  |  |  | 56.7 |  |  |  | 35,553,838 |  |  |  | 85.9 |  |
| Depreciation and Amortization |  |  | 6,463,248 |  |  |  | 4.6 |  |  |  | 6,331,847 |  |  |  | 8.7 |  |  |  | 131,401 |  |  |  | 2.1 |  |
| Professional service fees |  |  | 35,798,987 |  |  |  | 25.6 |  |  |  | 1,272,893 |  |  |  | 1.7 |  |  |  | 34,526,094 |  |  |  | 2,712.4 |  |
| Office |  |  | 1,900,626 |  |  |  | 1.4 |  |  |  | 2,039,932 |  |  |  | 2.8 |  |  |  | (139,306 | ) |  |  | (6.8 | ) |
| Taxes and surcharges |  |  | 6,789,028 |  |  |  | 4.8 |  |  |  | 6,537,346 |  |  |  | 9.0 |  |  |  | 251,682 |  |  |  | 3.8 |  |
| Other |  |  | 12,198,402 |  |  |  | 8.7 |  |  |  | 15,375,839 |  |  |  | 21.1 |  |  |  | (3,177,437 | ) |  |  | (20.7 | ) |
| **Total** |  |  | **140,086,062** |  |  |  | **100.0** |  |  |  | **72,939,790** |  |  |  | **100.0** |  |  |  | **67,146,272** |  |  |  | **92.1** |  |

***Impairment loss on inventory, property, plant and equipment and other assets***

Impairment loss on inventory, property, plant and equipment and other assets increased by 1,718.7% from RMB8.7 million for the fiscal year ended March 31, 2023 to RMB157.4 million ($22.2 million) for the fiscal year ended March 31, 2024. The increase in impairment loss on inventory, property, plant and equipment and other assets was primarily attributable to (i) impairment loss on inventory increased by RMB69.7 million due primarily to COVID-related disruptions affecting the Company’s manufacturing operations and production and impairment for raw material used for R&D in COVID vaccines. (ii) impairment loss on property, plant and equipment increased by RMB80.2 million attributed to write-down of PP&E related to COVID equipment, offset by a decrease of RMB1.1 million in impairment loss on other assets, primarily of credit losses on accounts receivable.

The following table sets forth a breakdown of our impairment loss on inventory, property, plant and equipment and other assets in absolute amount and as a percentage of the total impairment loss on inventory and other assets for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2024** | | | | | |  |  | **2023** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Impairment loss on other assets |  |  | 7,507,036 |  |  |  | 4.8 |  |  |  | 8,655,487 |  |  |  | 100.0 |  |  |  | (1,148,451 | ) |  |  | (13.3 | ) |
| Impairment loss on inventory |  |  | 69,671,843 |  |  |  | 44.3 |  |  |  | - |  |  |  | - |  |  |  | 69,671,843 |  |  |  | NM |  |
| Impairment loss on property, plant and equipment |  |  | 80,236,996 |  |  |  | 50.9 |  |  |  | - |  |  |  | - |  |  |  | 80,236,996 |  |  |  | 100.0 |  |
| **Total** |  |  | **157,415,875** |  |  |  | **100.0** |  |  |  | **8,655,487** |  |  |  | **100.0** |  |  |  | **148,760,388** |  |  |  | **1,718.7** |  |

Our impairment loss on other assets, primarily credit losses on trade receivables, were RMB7.5 million for the fiscal year ended March 31, 2024, a decrease of RMB1.1 million or 13.3% from RMB8.7 million for 2023. Expected credit losses are determined based on individual account analysis, historical collection trend, and best estimate of specific losses on individual exposures. We deemed accounts receivables and other receivables as uncollectible after all means of collection have been exhausted and the likelihood of collection is not probable.

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Our trading terms with our customers are mainly on a 120-days credit term. In practice, the credit term is normally 180 to 360 days.

The days sales outstanding increased by 43 days, or 16.4%, from 259 days for the fiscal year ended March 31, 2023 to 301 days for the fiscal year ended March 31, 2024. The increase in days sales outstanding was primarily due to the impact of COVID-19.

***Other income (expenses)***

We recorded other expenses, net of RMB9.4 million ($1.3 million) for the fiscal year ended March 31, 2024, as compared to RMB5.0 million for the fiscal year ended March 31, 2023, primarily attributable to (1) a decrease of RMB5.4 million in government grants; (2) an increase of RMB13.5 million in financial expense due to increase in interest expense of RMB12.5 million for a loan from R-Bridge and RMB3.0 million for other bank loans; offset by increase in bank interest income of RMB1.9 million; (3) an increase of RMB4.4 million in fair value changes of warrant liability; and (4) an increase of RMB10.0 million in other income, net due primarily to a termination of R&D in COVID-19 vaccine entrusted to a third party. Considering this COVID-19 vaccine did not receive approval, the final payment of RMB10.0 million did not need to be paid according to the contract.

***Income tax expense***

Our PRC subsidiaries are subject to income taxes in China on their taxable income calculated at a tax rate in accordance with the relevant income tax laws and regulations. We determine deferred taxes for each tax-paying entity in each tax jurisdiction. The potential tax benefits arising from the losses incurred by the subsidiaries have been recorded in our financial statements. Our income tax benefit increased from income tax expense of RMB1.1 million in the fiscal year ended March 31, 2023 to income tax benefit of RMB21.7 million ($3.1 million) in the fiscal year ended March 31, 2024, primarily due to the increase in deferred tax assets from write-down of inventories to net realizable value and impairment of property, plant and equipment in the year ended March 31, 2024.

We evaluate our valuation allowances requirements at each reporting period by reviewing all available evidence, both positive and negative, and considering whether, based on the weight of that evidence, a valuation allowance is needed. When a change in circumstances causes a change in management’s judgment about the ability to realize deferred tax assets, the impact of the change on the valuation allowance is generally reflected in income from operations. The future realization of the tax benefit of an existing deductible temporary difference ultimately depends on the existence of sufficient taxable income of the appropriate character within the carry forward period available under applicable tax law.

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***Net loss***

As a result of the foregoing, we recognized net loss of RMB433.5 million ($61.1 million) and RMB145.5 million for the fiscal years ended March 31, 2024 and 2023, respectively.

***Research and development expenses***

R&D expenses decreased by 5.0% from RMB318.7 million for the fiscal year ended March 31, 2023 to RMB302.8 million ($42.7 million) for the fiscal year ended March 31, 2024. The decrease in R&D expenses was primarily attributable to (i) a decrease of RMB4.5 million in testing and clinical trial fees associated with COVID-19 vaccines; (ii) a decrease of RMB11.4 million in employee benefits driven by optimization of staffing; and partially offset by an increase of RMB5.0 million in depreciation and amortization for property, plant and equipment and intangible assets used for R&D purpose.

The following table sets forth a breakdown of our R&D expenses in amount and as a percentage of total R&D expenses for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2024** | | | | | |  |  | **2023** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| Testing and clinical trial fees |  |  | 210,997,087 |  |  |  | 69.7 |  |  |  | 215,474,939 |  |  |  | 67.6 |  |  |  | (4,477,852 | ) |  |  | (2.1 | ) |
| Employee benefits |  |  | 56,716,238 |  |  |  | 18.7 |  |  |  | 68,073,077 |  |  |  | 21.4 |  |  |  | (11,356,839 | ) |  |  | (16.7 | ) |
| Depreciation and amortization |  |  | 20,749,231 |  |  |  | 6.9 |  |  |  | 15,736,087 |  |  |  | 4.9 |  |  |  | 5,013,144 |  |  |  | 31.9 |  |
| Consulting service fees |  |  | 9,058,949 |  |  |  | 3.0 |  |  |  | 9,772,154 |  |  |  | 3.1 |  |  |  | (713,205 | ) |  |  | (7.3 | ) |
| Office and leasing |  |  | 1,190,874 |  |  |  | 0.4 |  |  |  | 1,109,292 |  |  |  | 0.3 |  |  |  | 81,582 |  |  |  | 7.4 |  |
| Other |  |  | 4,088,613 |  |  |  | 1.4 |  |  |  | 8,534,977 |  |  |  | 2.7 |  |  |  | (4,446,364 | ) |  |  | (52.1 | ) |
| **Total** |  |  | **302,800,992** |  |  |  | **100.0** |  |  |  | **318,700,526** |  |  |  | **100.0** |  |  |  | (15,899,534 | ) |  |  | (5.0 | ) |

The following table below sets forth a breakdown of our key R&D projects.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **2024** | | | | | |  |  | **2023** | | | | | |  |  | **Variance** | | | | | |  |
|  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |  | **RMB** | |  |  | **%** | |  |
| PIKA rabies vaccine |  |  | 128,995,501 |  |  |  | 42.6 |  |  |  | 60,017,584 |  |  |  | 18.8 |  |  |  | 68,977,917 |  |  |  | 114.9 |  |
| PIKA Recombinant COVID-19 vaccine |  |  | 90,305,820 |  |  |  | 29.8 |  |  |  | 212,197,698 |  |  |  | 66.6 |  |  |  | (121,891,878 | ) |  |  | (57.4 | ) |
| PIKA HBV vaccines |  |  | 42,233,799 |  |  |  | 13.9 |  |  |  | 12,794,983 |  |  |  | 4.0 |  |  |  | 29,438,816 |  |  |  | 230.1 |  |
| YSJATM rabies vaccine |  |  | 21,293,796 |  |  |  | 7.0 |  |  |  | 5,949,199 |  |  |  | 1.9 |  |  |  | 15,344,597 |  |  |  | 257.9 |  |
| PIKA adjuvant |  |  | 8,237,970 |  |  |  | 2.7 |  |  |  | 7,979,196 |  |  |  | 2.5 |  |  |  | 258,774 |  |  |  | 3.2 |  |
| PIKA YS-0N-001 |  |  | 7,237,524 |  |  |  | 2.4 |  |  |  | 9,201,004 |  |  |  | 2.9 |  |  |  | (1,963,480 | ) |  |  | (21.3 | ) |
| Other |  |  | 4,496,582 |  |  |  | 1.5 |  |  |  | 10,560,862 |  |  |  | 3.3 |  |  |  | (6,064,280 | ) |  |  | (57.4 | ) |
| **Total** |  |  | **302,800,992** |  |  |  | **100.0** |  |  |  | **318,700,526** |  |  |  | **100.0** |  |  |  | **(15,899,534** | **)** |  |  | **(5.0** | **)** |

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|  |  |  |
| --- | --- | --- |
|  | **B.** | **Liquidity and Capital Resources** |

The following table sets forth a summary of our cash flows for the periods indicated.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Fiscal Years Ended March 31** | | | | | | | | | | | | | |  |
|  |  | **2025** | | | | | |  |  | **2024** | |  |  | **2023** | |  |
|  |  | **RMB** | |  |  | **US$** | |  |  | **RMB** | |  |  | **RMB** | |  |
| Net cash used in operating activities |  |  | (120,981,727 | ) |  |  | (16,854,048 | ) |  |  | (295,229,603 | ) |  |  | (182,469,396 | ) |
| Net cash used in investing activities |  |  | (17,006,500 | ) |  |  | (2,369,187 | ) |  |  | (44,250,714 | ) |  |  | (56,981,720 | ) |
| Net cash provided (used in) by financing activities |  |  | (3,580,946 | ) |  |  | (498,864 | ) |  |  | 205,261,352 |  |  |  | 317,449,926 |  |
| Effect of foreign exchange rate on cash and cash equivalents |  |  | 2,502,908 |  |  |  | 348,682 |  |  |  | 10,400,371 |  |  |  | 21,303,512 |  |
| Net (decrease) increase in cash and cash equivalents |  |  | (139,066,265 | ) |  |  | (19,373,417 | ) |  |  | (123,818,594 | ) |  |  | 99,302,322 |  |
| Cash and restricted cash at the beginning of the fiscal year |  |  | 246,551,231 |  |  |  | 34,347,222 |  |  |  | 370,369,825 |  |  |  | 271,067,503 |  |
| Cash and restricted cash at the end of the fiscal year |  |  | **107,484,966** |  |  |  | **14,973,805** |  |  |  | **246,551,231** |  |  |  | **370,369,825** |  |

We have historically financed our operations primarily through issuance of ordinary and preferred shares, issuance of convertible securities and cash generated from sales of our vaccines. Our primary requirements for liquidity and capital are to finance working capital, capital expenditures and general corporate purposes as well as investment in research and development and potential mergers and acquisition opportunities. We have experienced net losses and negative cash flows from operations. As discussed in Note 2 to the audited CFS appearing elsewhere in this Annual Report, those conditions combined with other factors raised substantial doubt about our ability to continue as a going concern for the next 12 months.

As of March 31, 2025, 2024 and 2023, our principal source of liquidity was our cash balance of RMB107.5 million ($15.0 million) and RMB246.6 million and RMB370.4 million, respectively, which was held for working capital purposes. We incurred a net loss after tax of RMB100.0 million ($13.9 million), RMB433.5 million and RMB145.5 million for the fiscal years ended March 31, 2025, 2024 and 2023, respectively.

Our primary uses of cash are to fund the development of our product candidates, our clinical trials, our construction of research and manufacturing facilities, purchase of equipment, compensation of key personnel, administrative expenses and other recurring expenses. Our net cash used in operating activities was RMB121.0 million ($16.9 million) and RMB295.2 million, RMB182.5 million in the fiscal years ended March 31, 2025, 2024 and 2023, respectively, primarily due to R&D and administrative expenses. Our operating cash flow will continue to be affected by our R&D expenses, in particular clinical trial fees for our product candidates, and administrative expenses. We have historically primarily funded our working capital requirements through proceeds from equity and debt financing. And our proceeds from the Business Combination are mainly used for overseas clinical trial and operations, while proceeds from bank loans is mainly used for operations of PRC subsidiaries.

We plan to use the outstanding cash, together with bank borrowings and cash from operating activities, to primarily fund our future operations. We plan to use proceeds from the Business Combination for overseas clinical trial and operations, and proceeds from bank loans for operations of PRC subsidiaries. However, if the commercialization of our marketed product and product candidates is delayed or terminated, or if expenses increase, we may need to obtain additional financing to fund our operations.

Our ability to obtain additional financing from exercise of Warrants may be limited. There is no assurance that the holders of the Warrants will elect to exercise any of the Warrants, which could impact our liquidity position. Whether holders of Warrants will exercise their Warrants, and therefore the amount of cash proceeds we would receive upon exercise, is dependent upon the trading price of the ordinary shares. Each Warrants is exercisable for 0.1 Ordinary Share at $11.5. Therefore, if and when the trading price of the ordinary shares is less than $115.0, we expect that holders of Warrants would not have the financial incentive to exercise their Warrants. We could receive up to $192.6 million if all of the Warrants are exercised for cash, but we would only receive such proceeds if and when the holders of Warrants exercise the Warrants. The Warrants may not be or remain in the money during the period they are exercisable and prior to their expiration and, therefore, it is possible that the Warrants may not be exercised prior to their maturity on March 15, 2028, even if they are in the money, and as such, may expire worthless with minimal proceeds received by us, if any, from the exercise of Warrants. To the extent that any of the Warrants are exercised on a “cashless basis,” we will not receive any proceeds upon such exercise. As a result of the above and coupled with the level of Redemption Rate, we do not expect to rely on the cash exercise of Warrants to fund our operations. Instead, we intend to rely on other sources of cash discussed elsewhere in this registration statement to continue to fund our operations. See “Item 3. Key Information—D. Risk Factors—Risks Related to Our Financial Position and Working Capital Need—We may need to obtain substantial additional financing to fund our operations, and a failure to obtain necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.”

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Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, we believe our liquidity requirements will be satisfied by cash generated from our operations and financing activities. As of March 31, 2025, 2024 and 2023, our working capital was RMB17.5 million ($2.4million) and RMB100.9 million and RMB377.2 million, respectively.

***Operating activities***

Cash flows from operating activities represent the cash receipts and disbursements related to our all activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for non-cash operating items such as depreciation, and stock-based compensation, as well as changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our results of operations.

Net cash used in operating activities of RMB121.0 million ($16.9 million) for the fiscal year ended March 31, 2025 was primarily driven by a net loss for the fiscal year of RMB100.0 million ($13.9 million) adjusted for certain non-cash items, which included deferred income taxes of RMB4.3 million ($0.6 million), depreciation of RMB29.7 million ($4.1 million), amortization of intangible assets of RMB6.9 million ($1.0 million), loss on disposal of property and equipment of RMB9.8 million ($1.4 million), provision for impairment of plant of RMB17.8 million ($2.5 million), provision for impairment of intangible assets of RMB10.4 million ($1.5 million), provision for impairment of other assets, non-current of RMB5.6 million ($0.8 million), share-based compensation expense of RMB13.6 million ($1.9 million), bad debt provision of trade receivable and inventories of RMB2.9 million ($0.4 million), non-cash lease expense of RMB3.1 million ($0.4 million), and increase of fair value change of warrant liabilities of RMB1.1 million ($0.2 million). The net changes in operating assets and liabilities of RMB120.8 million ($16.8 million) were primarily related to an increase in inventories of RMB24.2 million ($3.4 million) due to slower raw material procurement, an increase in trade receivables of RMB59.6 million ($8.3 million) due to increase in revenues, a decrease in prepaid expenses and other current assets of RMB7.5 million ($1.0 million) due primarily to the gradual delivery and settlement of advance payments made in prior years during the fiscal year of 2025, alongside our management’s efforts to enhance capital utilization efficiency by reducing advance payments scale to free up cash flow capacity. Concurrently, management enhanced fund utilization efficiency by reducing the scale of advance payments in order to free up cash flow capacity. A decrease in accounts payable of RMB18.2 million ($2.5 million) due to management’s optimization of procurement processes, a decrease in deferred government grants of RMB4.6 million ($0.6 million), and a decreased in operating lease liabilities of RMB5.3 million ($0.7 million).

Net cash used in operating activities of RMB295.2 million ($41.6 million) for the fiscal year ended March 31, 2024 was primarily from a net loss for the fiscal year of RMB433.5 million ($61.1 million) adjusted for certain non-cash items, which included deferred income taxes benefit of RMB21.7 million ($3.1 million), depreciation of RMB35.4 million ($5.0 million), amortization of intangible assets of RMB6.8 million ($1.0 million), loss on disposal of property, plant and equipment of RMB13,135 ($1,851), provision for impairment of plant of RMB80.2 million ($11.3 million), share-based compensation expense of RMB9.8 million ($1.4 million), bad debt provision of trade receivable and inventories of RMB5.0 million ($0.7 million), write-down of inventories to net realizable value of RMB68.2 million ($9.6 million), non-cash lease expense of RMB4.8 million ($0.7 million), and increase of fair value change of warrant liabilities of RMB1.1 million ($0.2 million). The net changes in operating assets and liabilities of RMB73.6 million ($10.4 million) were primarily related to an increase in inventories of RMB86.3 million ($12.2 million) due to increase in production batches, in increase in trade receivables of RMB13.9 million ($2.0 million) due to decrease in sales volume resulting from batch approvals and doses available for sale drawdown affected by COVID-19, an increase in prepaid expenses and other current assets of RMB5.3 million ($0.7 million) due primarily to prepayment for patent, a decrease in trade payables of RMB12.7 million ($1.8 million) due primarily to a termination of R&D entrusted to a third party and payment to another third party for R&D, an increase in accrued expenses and current liabilities of RMB53.2 million ($7.5 million) due to promotion fee to expand the access to district and county CDCs and hospitals, a decrease in deferred government grants of RMB3.6 million ($0.5 million) and a decrease in lease liabilities of RMB5.1 million ($0.7 million).

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Net cash used in operating activities of RMB182.5 million for the fiscal year ended March 31, 2023 was primarily from a net loss for the fiscal year of RMB145.5 million adjusted for certain non-cash items, which included deferred income taxes RMB1.1 million, depreciation of RMB29.7 million, amortization of intangible assets of RMB7.0 million, share- based compensation expense of RMB3.5 million, bad debt provision of trade receivable and inventories of RMB10.8 million, reversal of inventories to net realizable value of RMB0.7 million, non-cash lease expense of RMB4.4 million, and increase of fair value change of warrant liabilities of RMB0.02 million. The net changes in operating assets and liabilities of RMB92.7 million were primarily from an increase in inventories of RMB18.2 million due to increase in production batches, an increase in trade receivables of RMB165.2 million from increased sales of the rabies vaccine in 2023 fiscal year, a decrease in prepaid expenses and other current assets of RMB9.0 million due primarily to increased prepayments for construction in progress, an increase in trade payables of RMB49.6 million as a result of extending the accounting period for customers, an increase in accrued expenses and current liabilities of RMB43.0 million due to RMB22.7 million of promotion fee to expand the access to district and county CDCs and hospitals and RMB29.3 million of marketing deposit and transportation fees resulting from expanded sales, which were partially offset by decrease in deferred government grants of RMB6.4 million, and payment of lease liabilities of RMB4.6 million.

***Investing activities***

Cash flows used in investing activities primarily relate to purchase of property plant and equipment, acquisition of a subsidiary (net of cash acquired), investment in joint ventures as well as purchase of intangible assets.

Net cash used in investing activities was RMB17.0 million ($2.4 million) for the fiscal year ended March 31, 2025, which consisted of payment for purchase of items of property, plant and equipment of RMB12.7 million ($1.8 million) and payment for purchase of intangible assets of RMB5.1 million ($0.7 million).

Net cash used in investing activities was RMB44.2 million ($6.2 million) for the fiscal year ended March 31, 2024, which consisted of payment for purchase of items of property, plant and equipment.

Net cash used in investing activities was RMB57.0 million ($8.3 million) for the fiscal year ended March 31, 2023, which consisted primarily of payment for purchase of items of property, plant and equipment of RMB52.8 million ($7.7 million) and partial payment for purchase of intangible assets of RMB4.3 million ($0.6 million).

***Financing activities***

Net cash used in financing activities was RMB3.6 million ($0.5 million) for the fiscal year ended March 31, 2025, which consisted primarily of RMB334.8 million ($46.6 million) from bank loans and other borrowings, partially offset by RMB338.4 million ($47.1 million) in repayment of bank loans and other borrowings.

Net cash generated from financing activities was RMB205.3 million ($28.9 million) for the fiscal year ended March 31, 2024, which consisted primarily of RMB284.2 million ($40.1 million) from issuance of ordinary shares and RMB337.9 million ($47.6 million) from bank loans and other borrowings, partially offset by RMB416.8 million ($58.7 million) in repayment of bank loans and other borrowings.

Net cash generated from financing activities was RMB317.4 million ($46.2 million) for the fiscal year ended March 31, 2023, which consisted primarily of RMB252.5 million ($36.7 million) in the Business Combination, partially offset by RMB35.9 ($5.2 million) in offering cost, and RMB247.4 million ($36.0 million) in proceeds from bank and other borrowings, partially offset by RMB338.4 million ($47.1 million) in repayment of bank.

**Contractual Obligations**

On September 13, 2021, LakeShore Group entered into a credit facility of RMB100.0 million with China Guangfa Bank Co., Ltd. Shenyang Branch for three years to finance our working capital requirements. LakeShore Group drew RMB19.8 million from April 18, 2024 to May 17, 2024, with interest at 4%-4.5%, which was due on September 10, 2024. On September 9, 2024, LakeShore Group repaid RMB38.2 million. As of March 31, 2025, LakeShore Group has repaid it fully.

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On July 12, 2021, LakeShore Group entered into a credit facility of RMB140.0 million with Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch for three years to finance its working capital requirements. On September 12, 2023, LakeShore Group entered into another credit facility of RMB85.0 million with Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch for three years to finance its working capital requirements. From April 12, 2024 to March 20, 2025, LakeShore Group repaid RMB45.0 million. As of March 31, 2025, the balance of RMB38.4 million ($5.4 million) was outstanding.

On November 8, 2022, LakeShore Group borrowed RMB26.0 million with interest at 5.00% from Zhongguancun Technology Leasing Co., Ltd for 36 months. LakeShore Group shall repay RMB722,222 monthly from December 15, 2022 to October 15, 2025 and pay the last repayment of RMB722,230 on November 7, 2025. LakeShore Group repaid RMB11.6 million from December 2022 to March 2024 and 8.7 million from April 2024 to March 2025. As of March 31, 2025, the balance of RMB5.8 million ($0.8 million) was outstanding.

On January 13, 2023, LakeShore Group entered into a credit facility of RMB40.0 million with China CITIC Bank Shenyang Tiexi Branch, due on May 29, 2024, to finance its working capital requirements. On May 29, 2024, LakeShore Group repaid RMB12.4 million. As of March 31, 2025, LakeShore Group repaid it fully.

From March 17, 2023 to November 15, 2023, LakeShore Group borrowed RMB43.8 million in total with interest at 4.0% from China Construction Bank, Shenyang Heping Branch. The loans will be due from July 24, 2024 to November 14, 2025. From July 22, 2024 to December 5, 2024, LakeShore Group repaid RMB39.0 million. As of March 31, 2025, an balance of RMB4.8 million ($0.7 million) was outstanding.

On July 20, 2023, LakeShore Group borrowed RMB712,400 with interest at 3.90% from China Construction Bank Shenyang Heping Branch for one year. On July 18, 2024, LakeShore Group repaid RMB712,400. As of March 31, 2025, LakeShore Group has repaid it fully.

On November 15, 2023, LakeShore Group borrowed RMB6.9 million from China CITIC Bank Shenyang Tiexi Branch to finance working capital requirements, with interest at 4.55%. The loan will be due from May 15, 2024 to November 15, 2025. From May 15, 2024 to November 13, 2024, LakeShore Group repaid RMB1.4 million. As of March 31, 2025, the balance of RMB5.5 million ($0.8 million) was outstanding.

On January 8, 2024, LakeShore Group borrowed RMB4.5 million with interest at 4.55% from China CITIC Bank Shenyang Tiexi Branch to finance working capital requirements. The loan will be due from July 8, 2024 to January 8, 2026. From July 4, 2024 to January 7, 2025, LakeShore Group repaid RMB0.9 million. As of March 31, 2025, the balance of RMB3.6 million ($0.5 million) was outstanding.

On January 18, 2024, LakeShore Group borrowed RMB4.4 million with interest at 4.55% from China CITIC Bank Shenyang Tiexi Branch to finance working capital requirements. The loan will be due from July 18, 2024 to January 18, 2026. From July 17, 2024 to January 16, 2025, LakeShore Group repaid RMB0.88 million. As of March 31, 2025, the balance of RMB3.5 million ($0.5 million) was outstanding.

From August 16, 2023 to September 18, 2023, LakeShore Group borrowed RMB29.8 million with interest at 4.00% from Industrial Bank Shenyang Branch for one year. The loan will be due from August 15, 2024 to September 17, 2024. From August 14, 2024 to September 13, 2024, LakeShore Group repaid RMB29.8 million. As of March 31, 2025, LakeShore Group has repaid it fully.

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On March 16, 2022, LakeShore Group entered into a facility agreement with R-Bridge Healthcare Fund, LP (“R-Bridge”), as agent, to finance RMB274,868,000 ($40,000,000) for 54 months with interest at 4.00% (“R-Bridge Loan”). On December 27, 2023, HK Yisheng received a letter from R-Bridge (the “R-Bridge Letter”), notifying the Company that it has reason to believe HK Yisheng defaulted under financial covenants and other obligations under the facility agreement, and under the instructions of the lenders to urge the Company to consider and reach an amicable solution with the lenders, including, without limitation, repaying the loan of $40.0 million in full, as soon as possible. The Company repaid $15.0 million, $10.0 million and $18.1 million respectively in February, March and April, 2024. As of March 31, 2025, LakeShore Group has repaid its full amount of $40.0 million and accrued interest of $3.1 million.

From July 7, 2023 to January 16, 2024, LakeShore Group borrowed RMB30.0 million with interest at 4.0% from Minsheng Bank Shenyang Huanghe Street Branch, due from July 7, 2024 to January 16, 2025. From July 5, 2024 to January 15, 2025, LakeShore Group repaid RMB30.0 million. As of March 31, 2025, LakeShore Group has repaid it fully.

From August 14, 2023 to September 14, 2023, LakeShore Group borrowed RMB20.0 million with interest at 4.25% from Industrial Bank Shenyang Branch for about three years. The loan will be due from July 31, 2026 to September 3, 2026. As of March 31, 2025, the balance of RMB20.0 million ($2.8 million) was outstanding.

On May 29, 2023, LakeShore Group borrowed RMB40.0 million with interest at 4.80% from CITIC Financial Leasing Co., Ltd for three years. The loan will be due on May 29, 2026. From August 15, 2023 to February 14, 2025, LakeShore Group repaid RMB22.7 million. As of March 31, 2025, the balance of RMB17.3 million ($2.4 million) was outstanding, of which RMB13.8 million ($1.9 million) will due within one year.

From May 29, 2024 to March 20, 2025, LakeShore Group borrowed RMB311.4 million with interest at 5.0% from Beijing Huarui Jingkai Real Estate Co., Ltd. The loan will be due on December 31, 2025. As of March 31, 2025, the balance of RMB311.4 million ($43.4 million) was outstanding.

On March 26, 2025, LakeShore Group borrowed RMB3.6 million with interest at 5.0% from Apex Prospect Limited. The loan will be due on February 17, 2026. As of March 31, 2025, the balance of RMB3.6 million ($0.5 million) was outstanding.

LakeShore Group recorded RMB16.7 million, RMB47.5 million and RMB32.0 million of interest expense for the years ended March 31, 2025, 2024 and 2023, respectively.

**Lease liabilities**

A summary of our operating lease commitments as of March 31, 2025 as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Year Ended March 31,** |  | **(RMB)** | |  |  | **(US$)** | |  |
| 2026 |  |  | 470,319 |  |  |  | 65,521 |  |
| 2027 |  |  | - |  |  |  | - |  |
| **Total lease payments** |  |  | 470,319 |  |  |  | 65,521 |  |
| Less: Interest |  |  | (13,307 | ) |  |  | (1,854 | ) |
| **Present value of operating lease liabilities** |  |  | 457,012 |  |  |  | 63,667 |  |

As of March 31, 2025, the outstanding, discounted amount of lease liabilities was RMB457,012 ($63,667) which was for the lease agreements for one premises in China and one premises in Philippine.

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***Contingencies***

In 2018, Liaoning Yisheng filed a sales contract dispute with Hebei Defense Biological Products Supply Center. The Supreme People’s Court of Liaoning supported the Liaoning Yisheng’s claim the defendant Hebei Weifang should pay RMB2,465,807 for Liaoning Yisheng vaccine within 20 days after the judgment came into effect. As of the date of this report, LakeShore Group received RMB1,636,755 from Hebei Defense Biological Products Supply Center, and the balance of RMB829,052 may be received in 2026.

LakeShore Group was also involved in labor disputes as of March 31, 2025. As the proceedings are in the early stages or the second appeal, there is uncertainty regarding the timing or ultimate resolution of such matters, and therefore, an estimate for the reasonably possible loss or a range of reasonably possible losses cannot be made.

Since December 2023, the Company has been involved in two legal proceedings in the Cayman Islands against Mr. Yi Zhang, the former chairperson of the Board, and his associates.

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On December 22, 2023, the Grand Court of the Cayman Islands (the “Grand Court”) granted the Company an injunction order against Mr. Zhang, which restrained Mr. Zhang from, among other things, taking any steps to exercise any powers of, or hold himself out to be, chairperson of the Board. That injunction was discharged by the Grand Court on February 6, 2024. On February 16, 2024, the Company obtained another injunction order from the Grand Court which restrained Mr. Zhang and his associates, including Nan Zhang, Yun (Monica) Zhang, Lui Chi Keung and Jing Xian Li from, among other things, holding themselves out to be directors of the Company and from taking any steps to exercise any powers as though they were directors. On April 3, 2024, the Company filed an Amended Statement of Claim with the Grand Court in its proceedings against Mr. Zhang and his associates. The Amended Statement of Claim seeks various forms of declaratory and injunctive relief against the defendants as well as damages. On June 7, 2024, Mr. Zhang filed a Defence with the Grand Court which, among other things, alleges that certain present and former directors of the Company took steps to improperly oust Mr. Zhang from, and to seize control of, the Company and that certain present and former directors of the Company breached their fiduciary duties to the Company (which Mr. Zhang has pleaded will be the subject of separate derivative proceedings) and denies the Company’s entitlement to the relief the Company has claimed in its Amended Statement of Claim. On August 2, 2024, the Company filed and served its Reply by which the Company has, among other things, denied these allegations.

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In October 2024, Mr. Zhang filed a Writ of Summons and Statement of Claim (“Writ”) with the Grand Court against the Company and 13 of its current or former directors and Apex Prospect Limited (“Apex”), seeking, amongst other things, (i) declarations on the validity of certain actions of the Company’s Board taken since Mr. Zhang was removed as chairperson of the Board in December 2023; (ii) orders setting aside the February 2024 issue by the Company of 95,269,762 shares (which was the number of shares prior to the share consolidation, in consistency with the Writ) to Apex and any allotments of any shares issued by the Company pursuant to the share incentive plan approved by the Board in May 2024 or, alternatively, declaring that such share issuance and allotments were done for an improper purpose and in breach of the duties of the directors who approved them; (iii) orders that the Company’s Register of Members be rectified to delete any entries in respect of such share issuance and allotments; (iv) an injunction restraining Apex from exercising any rights attaching to the Company’s shares registered in its name or holding itself out to be a shareholder of the Company; (v) an injunction restraining the Company’s current directors from holding themselves out to be directors of the Company or exercising any powers as directors of the Company; (vi) an injunction restraining the Company and its Board from taking any steps to directly or indirectly allotting any further shares pursuant to the May 2024 share incentive plan or taking any actions which may result in the further dilution of Mr. Zhang’s shareholding and/or which would negatively affect the asset value and/or the share price of the Company; and (vii) damages against the director and former director defendants for unlawful means conspiracy against Mr. Zhang.

On October 31, 2024, Mr. Zhang applied to the Grand Court on an ex parte basis for an injunction to restrain the Company from (i) issuing new shares or causing Mr. Zhang’s shareholding to be diluted; and (ii) entering into any transactions or dealings with a value in excess of US$50,000 (other than in the ordinary course of business), each until Mr. Zhang had been given 7 day’s prior notice. On December 13, 2024, the Grand Court refused to hear that application on an ex parte basis. Mr. Zhang’s injunction application was heard on an inter partes basis on January 21 and 22, 2025 and dismissed by the Chief Justice of the Grand Court.

The Writ of Summons and Statement of Claim in the proceedings commenced by Mr. Zhang were amended on February 7, 2025 and Mr. Zhang discontinued his claims against 6 of the former director defendants on March 21, 2025. The Company and the remaining 7 director defendants filed their Defences to the Amended Statement of Claim on February 24, 2025 and March 17, 2025 respectively. Mr. Zhang filed his Replies to those Defences on March 31, 2025. On April 15, 2025, Mr. Zhang gave notice that he had changed his Cayman Islands attorneys. Mr. Zhang’s new attorneys later gave the Company notice that on or before June 6, 2025 he intended to seek leave to further amend the Amended Writ of Summons and Amended Statement of Claim.

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As of the date of this Annual Report, the legal proceedings in the two Cayman Islands are still ongoing and no further judgments have been rendered by the Grand Court. The parties have agreed that they will seek to have Cayman Islands proceedings consolidated and/or heard together going forward.

In May 2024, two entities controlled by Mr. Zhang (each, a “Claimant,” and collectively, the “Claimants”) filed arbitration claims respectively with the Kaifeng Arbitration Commission in China against Liaoning Yisheng. The Claimants sought an aggregate amount of RMB919 million ($128 million) of payment, primarily covering fees for R&D services of RMB198 million ($28 million) and accrued interests, borrowings and other fees of RMB721 million ($101 million) until full payment. The Claimants allege that Liaoning Yisheng owes them fees for research and development services from as early as 2002, and that the parties had entered into debt confirmation and repayment agreements respectively in March 2024, pursuant to which Liaoning Yisheng purportedly agreed to repay the Claimants approximately RMB723 million ($101 million) in the aggregate, including fees for R&D services of RMB198 million ($28 million) and accrued interests, borrowings and other fees of RMB525 million ($73 million) until full payment. Through the two aforementioned arbitration proceedings, the Claimants applied for pre-arbitration preservation of Liaoning Yisheng’s assets, requesting the of funds of up to RMB919 million ($128 million) in Liaoning Yisheng’s bank account (the “Freezing Applications”). Liaoning Yisheng applied to the court assisting the execution of the Freezing Applications to replace the subject assets of the Freezing Applications with its inventory of YSJATM rabies vaccine, certain machinery and equipment and properties, with had an appraisal value of approximately RMB919 milllion ($128 million). In consideration of the potential negative impact from the freezing of the bank accounts on Liaoning Yisheng’s cash flow and business operations, the court granted Liaoning Yisheng’s.

In May 2024, a Claimant filed arbitration claims with the Kaifeng Arbitration Commission in China against Beijing Yisheng. The Claimant alleged that Beijing Yisheng owed the Claimant certain fees and other amounts since 2021 due to historical reorganization transactions, and that the parties entered into debt confirmation and repayment agreements in March 2024, pursuant to which the Claimant claimed that Beijing Yisheng had agreed to repay the Claimant approximately RMB59 million (8 million) in the aggregate. The Claimant sought an arbitration award of RMB83 million ($12 million), which included the principal amount and other funds derived therefrom in payment from Beijing Yisheng.

As of the date of this Annual Report, the Kaifeng Arbitration Commission did not issue awards on these three cases. For the above cases there is uncertainty regarding the timing or ultimate resolution of such matters, and therefore, an estimate for the reasonably possible loss or a range of reasonably possible losses cannot be made.

**Holding Company Structure**

We are a holding company with no business operations. We conduct a substantial portion of our business and operations through our PRC subsidiaries, in particular, Liaoning Yisheng and Beijing Yisheng, and a substantial portion of our assets are located in China. As a result, our ability to pay dividends and to service any debt we may incur overseas largely depends upon dividends paid by our subsidiaries. If our subsidiaries incur debt on their own behalf in the future, the instruments governing their debt may restrict their ability to pay dividends to us.

In addition, our subsidiaries in China are permitted to pay dividends to their shareholder only out of their after-tax profits, if any, as determined in accordance with the Accounting Standards for Business Enterprise as promulgated by the Ministry of Finance of the PRC (the “PRC GAAP”). The aggregate Accumulated Deficit for our PRC subsidiaries as determined under the Accounting Standards for Business Enterprise were RMB515.7 million and RMB702.4 million and RMB696.7 million ($97.1 million) as of March 31, 2023, 2024 and 2025, respectively. In addition, pursuant to the relevant PRC laws, enterprises in the PRC have appropriate from their after-tax profit, as determined under PRC GAAP, to statutory common reserve funds. The appropriation to the statutory common reserve fund must be at least 10% of the after-tax profits calculated in accordance with PRC GAAP. Appropriation is not required if the reserve fund has reached 50% of the registered capital of such PRC enterprise. See “Item 4. Information on the Company—B. Business Overview—Regulations” for a detailed discussion of the PRC legal restrictions on dividends and our ability to transfer cash within our group. In addition, holders of our securities may potentially be subject to PRC taxes on dividends paid by it in the event we are deemed as a PRC resident enterprise for PRC tax purposes. See “Item 10. Additional Information—E. Taxation—PRC Taxation” for more details.

None of our PRC subsidiaries have issued any dividends or distributions to respective holding companies, including LakeShore Biopharma, or any investors as of the date of this Annual Report. Our subsidiaries in the PRC generate and retain cash generated from operating activities and re-invest it in our business. Historically, Liaoning Yisheng has also received equity financing from our shareholders to fund business operations of our PRC subsidiaries. In the fiscal years ended March 31, 2023, 2024 and 2025, we transferred cash to Liaoning Yisheng of nil, nil and nil, respectively. In the future, cash raised from overseas financing activities may be transferred by us through our subsidiaries outside China to our PRC subsidiaries via capital contribution and shareholder loans, as the case may be. Our PRC subsidiaries will pay dividends to their offshore shareholder to meet the capital needs of our business operations out of the PRC. For details about the applicable. PRC regulations and rules relating to such cash transfers through us and the associated risks, see “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China.”

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Cash is transferred among us, our offshore subsidiaries and our PRC subsidiaries, in the following manner: (i) funds are transferred to our PRC subsidiaries from us as needed through our subsidiaries outside China in the form of capital contributions or shareholder loans, as the case may be; and (ii) dividends or other distributions may be paid by our PRC subsidiaries to us through our subsidiaries outside China. Our subsidiaries in the PRC generate and retain cash generated from operating activities and re-invest it in our business. None of our subsidiaries outside China made distribution to certain shareholders. In the future, our ability to pay dividends, if any, to our shareholders and warrant holders and to service any debt we may incur will depend upon dividends paid by our subsidiaries. In the fiscal years ended March 31, 2023, 2024 and 2025, we did not transfer any cash to any of our PRC subsidiaries except for the cash transfers within us connection with the paid-in capital in our PRC subsidiaries, including the contribution of $1,008,768 by HK Yisheng to Beijing Yisheng’s paid-in capital during the fiscal year ended March 31, 2024.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements. We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties. We have not entered into any derivative contracts that are indexed to our shares and classified as shareholders’ equity or that are not reflected in our consolidated financial statements. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity, or market risk support to such entity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or that engages in leasing, hedging or R&D services with it.

**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) of the Exchange Act. Based on the assessment, our management has concluded that our internal control over financial reporting was not entirely effective as of March 31, 2025. For a summary of the material weaknesses identified and the measures that we have taken and are taking to remediate such deficiencies, see “Item 15. Controls and Procedures—Management’s Annual Report on Internal Control over Financial Reporting.”

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|  | **C.** | **Research and Development** |

See “Item 4. Information on the Company—B. Business Overview—Research and development team and activities” and “Item 4. Information on the Company—B. Business Overview—Intellectual Property.”

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|  | **D.** | **Trend Information** |

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events for the period from April 1, 2024 to March 31, 2025 that are reasonably likely to have a material effect on our operating revenues, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

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|  | **E.** | **Critical Accounting Estimates** |

Our consolidated financial statements (“CFS”) have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these CFS requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the CFS prospectively from the date of change in estimates.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are other items within our financial statements that require estimation but are not deemed critical, as defined above. Changes in estimates used in these and other items could have a material impact on our financial statements.

While our significant accounting policies are described in more detail in Note 3 to the audited CFS appearing elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

***Impairment of Long-lived Assets***

LakeShore Biopharma reviews long-lived assets, including definitive-lived intangible assets and property, plant and equipment, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. When such events occur, LakeShore Biopharma assesses the recoverability of the asset group based on the undiscounted future cash flows the asset group is expected to generate and recognizes an impairment loss when estimated undiscounted future cash flows expected to result from the use of the asset group plus net proceeds expected from disposition of the asset group, if any, is less than the carrying value of the asset group. If LakeShore Biopharma identifies an impairment, LakeShore Biopharma reduces the carrying amount of the asset group to its estimated fair value based on a discounted cash flow approach or, when available and appropriate, to comparable market values and the impairment loss, if any, is recognized in general and administrative expenses in the consolidated statements of operations. LakeShore Biopharma uses estimates and judgments in its impairment tests and if different estimates or judgments had been utilized, the timing or the amount of any impairment charges could be different. Asset groups to be disposed of would be reported at the lower of the carrying amount or fair value less costs to sell, and no longer depreciated. Impairment was recorded in impairment loss on inventory, property, plant and equipment and other assets on the consolidated statements of operations and comprehensive loss. We recorded RMB36,715,041 ($5,114,798) and RMB157,415,875 impairment loss on inventory, property, plant and equipment and other assets during the years ended March 31, 2025 and 2024, respectively.

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**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

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|  | **A.** | **Directors and Senior Management** |

The following table sets forth certain information relating to our directors and executive officers as of the date of this Annual Report. Our board of directors is comprised of seven directors.

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| **Name** |  | **Age** | |  |  | **Position** |
| Pierson Yue Pan |  |  | 43 |  |  | Director and Chairperson of the Board |
| Xu Wang |  |  | 54 |  |  | Director and Chief Executive Officer |
| Dr. Hui Shao |  |  | 57 |  |  | Director, President, Chief Business Officer and Vice Chairman of the Board |
| Rachel Yu |  |  | 50 |  |  | Director and Chief Financial Officer |
| Adam Zhao |  |  | 57 |  |  | Director |
| Thomas Xue |  |  | 52 |  |  | Director |
| Chunyang Shao |  |  | 61 |  |  | Director |
| Dr. Yuan Liu |  |  | 39 |  |  | Head of Vaccine Research |
| Zhiyuan Ran |  |  | 46 |  |  | Head of Marketing and Sales |
| Dr. Honggang Teng |  |  | 52 |  |  | Head of Production and Quality Management |

***Mr. Pierson Yue Pan*** has served as our director and chairperson of the board of directors since May 2025. He served as a member of the Board from February 2024 to May 2024. Mr. Pan is a senior executive with nearly 20 years of senior management experience and a strong track record of business success. He currently serves as the Deputy President and previously served as the Vice President at Monument Pacific Development Corp. since 2018, in charge of both its healthcare investment and real estate development business in California, the U.S. Prior to that, Mr. Pan worked as the Vice President of Business Development at Propriis, a real estate development company, from 2012 to 2018. From 2004 to 2011, he served as the General Manager of the African Market Division at China Civil Engineering Construction Company, a Fortune Global 500 enterprise. Mr. Pan holds an MBA from the University of California, Berkeley’s Hass School of Business and a bachelor’s degree in business administration from Shanghai University.

***Mr. Xu Wang*** has served as our chief operation officer from June 2024 to September 2024 and as our director and chief executive officer since September 2024. Mr. Wang has over twenty years of senior management and strong operational experience from a number of major pharmaceutical manufacturers, including GSK, Takeda, and others. Mr. Wang has served as the general manager at Xiamen Innovax Biotech Co., Ltd., where he led the production capacity expansion of HPV vaccine, since 2021. Prior to that, Mr. Wang worked at Takeda Pharmaceuticals from 2012 to 2020, where he managed its commercial-scale facilities in Guangzhou China and Singen Germany. From 2001 to 2012, Mr. Wang worked at Shanghai GSK Biologics. Mr. Wang was recognized as a Fujian Province Class A Talent and was a NMPA GMP Instructor. Mr. Wang obtained his Master of Science in Microbiology and a Bachelor of Science degree in Microbiology from Fudan University in 1998 and 1995, respectively.

***Dr. Hui Shao*** has served as our director and chief executive officer since December 2020 is currently serving as our director, president, chief business officer and vice chairman of the board. Dr. Shao served as the director, president and chief executive officer of Yisheng Biopharma from February 2018 to December 2020, and prior to that, as the chief financial officer and global business head of the same company since October 2010. Dr. Shao served as the senior vice president of finance and then the chief financial officer of Aoxing Pharmaceutical Company, Inc. from January 2007 to October 2010, where he was responsible for preparing financial statements in accordance with U.S. GAAP and SEC rules and regulations. From 2005 to 2007, Dr. Shao was a senior biotechnology analyst at Kamunting Street Capital Management in New York. From 2003 to 2005, Dr. Shao was a healthcare analyst at Mehta Partners in New York. Prior to that, Dr. Shao had spent five years as a principal scientist at Roche Pharmaceuticals, USA. Dr. Shao received his bachelor’s degree in chemistry from University of Science & Technology of China in 1991, his Ph.D. degree in bioorganic chemistry from University of California, San Diego in 1996, and an M.B.A. degree in finance and accounting from Stern School of Business, New York University in 2003. Dr. Shao is a chartered financial analyst (CFA) and AICPA holder in the State of Washington, the United States.

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***Ms. Rachel Yu*** has served as our director since December 2023 and our interim chief financial officer from June 2024 to September 2024 and has served as our chief financial officer since September 2024. Ms. Yu is a partner at Oceanpine Capital’s healthcare practice since May 2021, where she is responsible for formulating the overall investment strategies in the healthcare sector and taking day-to-day principal leadership responsibility in financial and operational management of financial team, investment team and portfolio companies. Prior to that, she was a partner at China Renaissance Group, where she worked from 2014 to 2021 and took the principal responsibility in deal sourcing, and conducting due diligence on investment targets, including financial and operational data, financial models and valuation and compliance. From 2012 to 2014, Ms. Yu served as vice president/head of China healthcare research at Gerson Lehman Group. Prior to that, Ms. Yu worked as an equity analyst at Maxim Group, Rodman & Renshaw, and Deutsche Bank Securities. Ms. Yu received her BSc from Guangdong Pharmaceutical University, her MSc from The University of Missouri School of Medicine, and her MBA from the University of Chicago Booth School of Business with concentrations in finance, accounting and entrepreneurship.

***Mr. Adam Zhao*** has served as our director since May 2024. Mr. Zhao is an experienced finance professional with extensive experience in capital markets, corporate finance, and strategic governance. He currently holds positions as an independent director at Zhangmen Education (NYSE: ZME) and Cloopen Group (NYSE: RAAS), focusing on enhancing corporate governance and maintaining compliance with audit standards. From 2015 to 2021, Mr. Zhao served as the CFO and Corporate Secretary at PapayaMobile in Beijing, where he was instrumental in their U.S. IPO process and managed significant financing rounds that shaped the company’s growth. His previous roles include serving as an independent director at Jumei International and eLong, where he was involved in financial oversight and corporate governance, contributing to successful privatization processes. Mr. Zhao holds an MBA with a focus on Finance and Accounting from the University of Illinois at Chicago and a bachelor’s degree in Economics from Beijing International Studies University. He is a Chartered Financial Analyst (CFA).

***Mr. Thomas Xue*** has served as our director since May 2024. Mr. Xue has served as the chief executive officer of McKindy Group since February 2023, taking charge of strategic planning, operations, and financial management. Mr. Xue also holds the position of Independent Director and Chairman of the Audit Committee at Techstar (HK: 7855). Mr. Xue also served as CFO at Deepwise Co., Ltd., where he managed the company’s financial strategies and operations from April 2021 to February 2023. He has held leadership roles in notable companies, including as Vice Chairman and Global Partner at Fosun Hive Group, and CFO and Global Partner at Fosun Group (HK: 00656). His career also includes significant tenures at AEI – Huatong Energy, KPMG, and Briggs & Stratton, focusing on risk management and audit services. Mr. Xue received his master’s degree in economics from Boston University in 2001, and a bachelor’s degree from Renmin University of China in 1997. He has been a member of American Institute of Certified Public Accountants since February 2002 and a member of American Institute of Internal Control since November 2006.

***Mr. Chunyang Shao*** has served as our director since May 2024. Mr. Shao is a partner at the law firm JunHe LLP and currently practices at its Shanghai office as the managing partner. Mr. Shao specializes in corporate, foreign investment, real estate, mergers and acquisitions (“M&A”), securities, infrastructure and project finance. Mr. Shao joined JunHe in April 2002 and has since represented various multinational corporations and investment funds on their investments and M&As in China. From 1995 to 2001, Mr. Shao worked in the London, Hong Kong and mainland China offices of major international law firms, including Simmons & Simmons (as Chinese legal counsel) and Sidley Austin (as a senior legal consultant), involved extensively in foreign direct investment, securities (including B-share, H-share, and red chip listing on the stock exchange in mainland China, Hong Kong, London and the U.S.), venture capital, project finance and real estate matters and representing a number of well-known multinational companies. Mr. Shao obtained his Bachelor and Master of Laws from East China University of Political Science and Law in 1987 and 2002, respectively.

***Dr. Yuan Liu*** has served as our head of vaccine research since January 2019. She is responsible for the R&D of vaccine adjuvant, including PIKA hepatitis B vaccine, human PIKA rabies vaccine and new adjuvant-based tumor vaccine under development. Dr. Liu also served as the project leader of R&D department of YS Group Xingye from July 2014 to January 2019 and subsequently has served as the vice president of research department of YS Group Xingye since January 2019. Dr. Liu has focused on the research of vaccine adjuvants for over 10 years. In 2016, she won the sponsorship of young backbone individual project by Beijing outstanding talent training fund. Dr. Liu received her Ph.D. degree in University of Chinese Academy of Sciences in July 2014. She received her bachelor’s degree in Sun Yat-sen University in July 2008.

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**Ms. Zhiyuan Ran** joined the company in January 2020 and has served as the Head of Marketing and Sales since November 2024, assuming full responsibility for the strategic planning and operational management of the marketing and sales department. Prior to joining the company, Ms. Ran held positions at renowned domestic and international pharmaceutical enterprises, including Sanofi, GlaxoSmithKline, and Watson Biologics, where she specialized in the promotion of various vaccines such as rabies vaccine, influenza vaccine, hepatitis A vaccine, hepatitis B (adult formulation) vaccine, Hib vaccine, and others. Leveraging her extensive expertise in vaccine products and years of experience in sales and marketing, Ms. Ran spearheaded the development of the company’s omni-channel market strategy and the optimization of business processes by focusing on the construction of a robust marketing system and driving business growth. Ms. Ran earned her Master’s degree in Public Health from the Chinese Center for Disease Control and Prevention in 2016 and her Bachelor’s degree in Microbial Pharmacy from Shenyang Pharmaceutical University in 2002.

***Dr. Honggang Teng*** has served as the general manager and head of production and quality management of Liaoning Yisheng since March 2024. Dr. Teng has over 20 years of R&D and manufacturing experience in monoclonal antibody, HAV and HBV vaccines, HPV vaccine, rabies vaccine and HIV/AIDS DNA vaccine programs. Prior to that, he served as the vice president of Jiangsu JDK Biotechnology Company Limited, responsible for overseeing manufacturing, research and development functions of the company. He served as the vice president of Liaoning Yisheng from August 2016 to March 2022 and head of production and quality management of Liaoning Yisheng from August 2016 to November 2018. Prior to joining us, Dr. Teng served as the production director in Chuangchun Zhuoyi Biological Co., Ltd from January 2012 to June 2015. From June 2007 to June 2009, he served as the general manager assistant and vice general manager in Yatai Bio-Pharmaceuticals Co., Ltd.

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|  | **B.** | **Compensation** |

In the fiscal year ended March 31, 2025, we paid RMB9.6 million and RMB0.9 million in cash compensation and benefits in kind to our directors and executive officers as a group, respectively, and we did not pay any cash compensation to our non-executive directors except for independent directors. Each of our directors and officers is entitled to reimbursement for all necessary and reasonable expenses properly incurred in the course of employment or service. We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors, except that our subsidiaries in the PRC are required by law to make contributions equal to certain percentages of each employee’s salary for his or her pension insurance, medical insurance, unemployment insurance and other statutory benefits and a housing provident fund. Our board of directors may determine compensation to be paid to the directors and the executive officers. The compensation committee will assist the directors in reviewing and approving the compensation structure for the directors and the executive officers.

For information regarding share awards granted to our directors and executive officers, see “—Share Incentive Plans.”

***Employment Agreements and Indemnification Agreements***

Each of the executive officers is party to an employment agreement with us. Under these agreements, the employment of each of executive officers is for a specified time period, and may be terminated for cause, at any time, for certain acts of the executive officer, such as continued failure to satisfactorily perform, willful misconduct or gross negligence in the performance of agreed duties, conviction or entry of a guilty or nolo contendere plea of any felony or any misdemeanor involving moral turpitude, or dishonest act that results in material to its detriment or material of the employment agreement. The employment may also be terminated without cause upon 60-to-120 day advance written notice. The executive officer may resign at any time with a 60-to-120 day advance written notice.

The employment agreements with the other executive officers also include confidentiality and non-disclosure restrictions and non-competition and non-solicitation restrictions that apply during employment for certain periods following termination of employment.

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***Share Incentive Plans***

*2020 Share Incentive Plan*

On December 31, 2020, LakeShore Group’s board of directors adopted the 2020 Share Incentive Plan for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with LakeShore Group. Pursuant to such plan, LakeShore Group can grant awards to directors, employees and consultants of LakeShore Group with rights to subscribe for up to 875,000 underlying ordinary shares of LakeShore Biopharma. As of the date of this report, (1) 457,298 shares as RSU incentive shares have been fully vested and issued to the respective directors and employees of LakeShore Group, and (2) 417,702 shares are reserved but not issued, among which, options to subscribe for 347,155 ordinary shares of LakeShore Biopharma are granted to certain senior management and employees of LakeShore Group but not exercised, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024.

The following summarizes the material terms of the 2020 Share Incentive Plan:

*Types of awards*. The types of awards that may be granted under the plan include share options, share appreciation rights, restricted share units and other awards approved by the plan administrator.

*Plan Administration*. The plan shall be subject to the administration of our Board or one or more committees or person as authorized and appointed by our Board. The plan administrator shall have the right to determine the participants to receive awards, the type and number of awards to be granted to each participant, and the terms and conditions of each award grant.

*Award Agreement*. Each award shall be evidenced by a written award agreement in the form approved by the plan administrator and executed on our behalf or as required by the plan administrator. The award agreement shall set forth the material terms and conditions of the award as established by the plan administrator consistent with the express limitations of the plan.

*Eligibility*. Persons eligible to participate in the plan will be those officers, employees and directors of any member of the proposed listing group, individual consultant or adviser as selected from time to time by the administrator of this plan. However, persons eligible to participate in the performance-based awards will be those officers and employees of any member of the proposed listing group.

*Vesting Schedule*. In general, the plan administrator determines the vesting schedule, which is specified in the relevant award agreement.

*Termination and amendment*. Unless terminated earlier, the plan has a term of 10 years. Our board of directors has the authority to amend or terminate the plan. However, no such action may adversely affect in any material way any awards previously granted without the prior written consent of the recipient.

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*The 2024 Share Incentive Plan*

On May 21, 2024, our board of directors adopted the 2024 Share Incentive Plan for the purpose of granting share-based awards to employees, directors and consultants to incentivize their performance and align their interests with the Company. The 2024 Share Incentive Plan was also approved by our shareholders at an extraordinary general meeting held on May 21, 2024. The maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2024 Share Incentive Plan is initially 571,306 ordinary shares, plus an annual increase on the first day of each fiscal year of the Company during the term of this plan commencing with the fiscal year beginning on April 1, 2025, by (i) an amount equal to 1% of the total number of ordinary shares issued and outstanding on the last day of the immediately preceding fiscal year, or (ii) such lesser number of ordinary shares as may be determined by the Board, provided that the numbers shall be equitably adjusted in the event of any share dividend, subdivision, reclassification, recapitalization, split, reverse split, combination, consolidation or similar transactions. Giving retroactive effect of Share Consolidation in October 2024.

*Amended 2024 Share Incentive Plan*

The 2024 Share Incentive Plan was amended in March 2025, as approved and authorized by our board of directors. To reflect the share consolidation effective on October 1, 2024, and the early utilization of the ordinary shares reserved for issuance under the 2024 Share Plan pursuant to the Evergreen Provision, the 2024 Award Pool under the Amended 2024 Share Incentive Plan was adjusted to 2,479,385 ordinary shares, par value US$0.0002 per share. The remainder of the Amended 2024 Share Incentive Plan remains the same as the 2024 Share Incentive Plan. As of the date of this report, (1) 750,000 shares as RSU incentive shares have been fully vested and issued to the respective directors and employees of LakeShore Group, and (2) 597,617 shares are reserved but not issued or outstanding, among which, options to subscribe for 101,732 ordinary shares of LakeShore Biopharma are granted to certain senior management of LakeShore Group but not exercised, (3) 956,938 shares are not reserved.

The following summarizes the material terms of the Amended 2024 Share Incentive Plan:

*Types of awards*. The types of awards that may be granted under the plan include share options, restricted share or restricted share units and other awards approved by the plan administrator.

*Plan Administration*. The plan shall be subject to the administration of our Board or the compensation committee of the Board. The plan administrator shall have the right to determine the participants to receive awards, the type and number of awards to be granted to each participant, and the terms and conditions of each award grant.

Award Agreement. Each award shall be evidenced by a written award agreement in the form approved by the plan administrator and executed on our behalf or as required by the plan administrator. The award agreement shall set forth the material terms and conditions of the award as established by the plan administrator consistent with the express limitations of the plan.

Eligibility. Persons eligible to participate in the plan will be employees, consultants and directors, as determined by the administrator of this plan.

Vesting Schedule. In general, the plan administrator determines the vesting schedule, which is specified in the relevant award agreement.

Termination and amendment. Unless terminated earlier, the plan has a term of 10 years. Our board of directors has the authority to amend or terminate the plan. However, no such action may adversely affect in any material way any awards previously granted without the prior written consent of the recipient.

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The following table summarizes, as of June 30, 2025, the number of ordinary shares underlying outstanding options, restricted share units and other equity awards that we granted to our directors and executive officers.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of Grantee** |  | **Ordinary Shares Underlying Equity Awards Granted** | |  |  | **Exercise Price Per Ordinary Share ($)** | |  |  | **Grant Date** |  | **Expiration Date** |
| Dr. Yuan Liu |  |  | 2,382 |  |  |  | 40.724 – 82.760 |  |  | December 31, 2020 |  | the 10th anniversary of the Grant Date |
| Ms. Zhiyuan Ran |  |  | 140 |  |  |  | 40.724 |  |  | December 31, 2020 |  | the 10th anniversary of the Grant Date |
| Ms. Rachel Yu |  |  | 203,464 |  |  |  | 1.225 |  |  | December 13, 2024 |  | the 10th anniversary of the Grant Date |
| Mr. Xu Wang |  |  | 203,464 |  |  |  | 1.225 |  |  | December 13, 2024 |  | the 10th anniversary of the Grant Date |
| Dr. Honggang Teng |  |  | 102,692 |  |  |  | 1.225 – 82.760 |  |  | December 31, 2020; April 01, 2025 |  | the 10th anniversary of the Grant Date |

Notes:

|  |  |  |
| --- | --- | --- |
|  | (1) | “\*” denotes less than 1.3% of our total outstanding ordinary shares. |

As of June 30, 2025, our employees other than our directors and executive officers as a group held 343,677 ordinary shares underlying outstanding options, restricted share units and other equity awards. The exercise price of the options we granted ranges from $21.956 to $82.760 per share.

|  |  |  |
| --- | --- | --- |
|  | **C.** | **Board Practices** |

**Board of Directors**

Our board of directors consists of seven directors. Of these seven directors, three are independent. The Articles provide that the minimum number of directors shall be three unless otherwise determined by our company in general meeting. A director is not required to hold any of our shares by way of qualification. A director may vote in respect of any contract or proposed contract or arrangement in which such director may be interested provided that (1) the nature of his/her interest is declared at a meeting of the directors, either specifically or by way of a general notice, and subject to the Nasdaq rules and disqualification by the chairperson of the relevant Board meeting, such director’s vote may be counted in the quorum at any meeting of directors at which any such contract or proposed contract or arrangement is considered, and (2) if such contract or arrangement is a transaction with a related party, such transaction has been approved by the audit committee. The directors may exercise all of our powers to raise or borrow money, mortgage or charge its undertaking, property and assets (present and future) and uncalled capital, and issue debentures or other securities whether outright or as security for our obligation or of any third party. None of our non-employee director has a service contract with us that provides for benefits upon termination of service.

**Board Committees**

Our Board has an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee’s members and functions are described below.

Our Board has determined that each of Mr. Adam Zhao, Mr. Thomas Xue and Mr. Chunyang Shao satisfies the requirements for an “independent director” within the meaning of the Nasdaq listing rules and the criteria for independence set forth in Rule 10A-3 of the Exchange Act.

***Audit Committee***

The audit committee consists of Mr. Adam Zhao, Mr. Thomas Xue and Mr. Chunyang Shao. Mr. Adam Zhao is the chairperson of the audit committee. Each of Mr. Adam Zhao, Mr. Thomas Xue and Mr. Chunyang Shao satisfies the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC.

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The audit committee oversees our accounting and financial reporting processes. The audit committee is responsible for, among other things:

|  |  |  |
| --- | --- | --- |
|  | ● | appointing the independent auditors and pre-approving all auditing and non-auditing services permitted to be performed by the independent auditors; |

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing with the independent auditors any audit problems or difficulties and management’s response; |

|  |  |  |
| --- | --- | --- |
|  | ● | discussing the annual audited financial statements with management and the independent auditors; |

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures and any steps taken to monitor and control major financial risk exposures; |

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing and approving all proposed related party transactions; |

|  |  |  |
| --- | --- | --- |
|  | ● | meeting separately and periodically with management and the independent auditors; |

|  |  |  |
| --- | --- | --- |
|  | ● | monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance. |

***Compensation Committee***

The compensation committee consists of Ms. Rachel Yu, Mr. Pierson Yue Pan and Dr. Hui Shao. Ms. Rachel Yu is the chairperson of the compensation committee.

The compensation committee is responsible for, among other things:

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing and approving, or recommending to the board for its approval, the compensation for our chief executive officer and other executive officers; |

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing and recommending to the board for determination with respect to the compensation of our non-employee directors; |

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing periodically and approving any incentive compensation or equity plans, programs or similar arrangements; and |

|  |  |  |
| --- | --- | --- |
|  | ● | the selection of compensation consultant, legal counsel or other adviser only after taking into consideration all factors relevant to that person’s independence from management. |

***Nominating and Corporate Governance Committee***

The nominating and corporate governance committee consists of Ms. Rachel Yu, Mr. Pierson Yue Pan and Dr. Hui Shao. Ms. Rachel Yu is the chairperson of the nominating and corporate governance committee.

The nominating and corporate governance committee is responsible for, among other things:

|  |  |  |
| --- | --- | --- |
|  | ● | selecting and recommending to our Board nominees for election by the shareholders or appointment by our Board; |

|  |  |  |
| --- | --- | --- |
|  | ● | reviewing annually with our Board the current composition of our Board with regard to characteristics such as independence, knowledge, skills, experience and diversity; |

|  |  |  |
| --- | --- | --- |
|  | ● | making recommendations on the frequency and structure of our Board meetings and monitoring the functioning of the committees of our Board; and |

|  |  |  |
| --- | --- | --- |
|  | ● | advising our Board periodically with regard to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to our Board on all matters of corporate governance and on any remedial action to be taken. |

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***Code of Business Conduct and Ethics***

We have Code of Business Conduct and Ethics applicable to our directors, officers and employees. We seek to conduct business ethically, honestly, and in compliance with applicable laws and regulations. Our Code of Business Conduct and Ethics sets out the principles designed to guide our business practices- compliance, integrity, respect and dedication. The code applies to all directors, officers, employees and extended workforce, including the Chairperson and Chief Executive Officer and Chief Financial Officer. Relevant sections of the code also apply to members of our Board. We expect our suppliers, contractors, consultants, and other business partners to follow the principles set forth in our code when providing goods and services to us or acting on our behalf.

|  |  |  |
| --- | --- | --- |
|  | **D.** | **Employees** |

As of March 31, 2025, we had 573 full-time employees. The following table sets forth the number of our full-time employees by function as of March 31, 2025.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Number** | |  |  | **%** | |  |
| Research and development |  |  | 112 |  |  |  | 19.5 |  |
| General and administrative |  |  | 89 |  |  |  | 15.5 |  |
| Manufacturing |  |  | 328 |  |  |  | 57.3 |  |
| Sales, marketing and patient services |  |  | 44 |  |  |  | 7.7 |  |
| **Total** |  |  | **573** |  |  |  | **100.0** |  |

As required under labor laws in different jurisdictions, we enter into individual employment contracts with our employees covering matters such as wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. In compliance with PRC regulations, we participate in various employee social security plans that are organized by applicable governments, including housing, pension, medical insurance, work-related injury and unemployment benefit plans. We are required under PRC laws to make contributions to employee benefit plans at specified percentages of the salaries.

Our success depends on our ability to attract, retain and motivate qualified personnel. As part of our retention strategy, we offer employees competitive salaries, performance-based cash bonuses, share-based compensation and other incentives. In order to maintain a competitive edge, we will continue to focus on attracting and retaining qualified professionals by providing an incentive-based and market-driven compensation structure that rewards performance and results. In addition to on-the-job training, we regularly provide management, technology, regulatory and other training to our employees through internally developed training programs or professional consultants.

We believe we maintain a good working relationship with our employees and we had not experienced any labor disputes that may materially adverse our business, operations and financial conditions or any difficulty in recruiting staff for our operations in the three fiscal years ended March 31, 2025 and up to the date of this Annual Report.

|  |  |  |
| --- | --- | --- |
|  | **E.** | **Share Ownership** |

The following table sets forth information regarding the beneficial ownership of our ordinary shares as of June 30, 2025 by:

|  |  |  |
| --- | --- | --- |
|  | ● | each person known by us to beneficially own 5.0% or more of the outstanding ordinary shares; |

|  |  |  |
| --- | --- | --- |
|  | ● | each of our executive officer or director; and |

|  |  |  |
| --- | --- | --- |
|  | ● | all of executive officers and directors as a group. |

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Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to, or the power to receive the economic benefit of ownership of, the securities. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares that the person has the right to acquire within 60 days are included, including through the exercise of any option or other right or the conversion of any other security. However, these shares are not included in the computation of the percentage ownership of any other person.

The beneficial ownership percentages set forth in the table below have been determined based on 41,212,693 ordinary shares issued and outstanding as of June 30, 2025.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Number** | |  |  | **%** | |  |
| **Directors and Executive Officers(1):** |  |  | |  |  |  | |  |
| Pierson Yue Pan |  |  | - |  |  |  | - |  |
| Xu Wang |  |  | - |  |  |  | - |  |
| Rachel Yu |  |  | - |  |  |  | - |  |
| Dr. Hui Shao(2) |  |  | 313,638 |  |  |  | 0.8 |  |
| Adam Zhao |  |  | - |  |  |  | - |  |
| Thomas Xue |  |  | - |  |  |  | - |  |
| Chunyang Shao |  |  | - |  |  |  | - |  |
| Dr. Zenaida Reynoso Mojares |  |  | - |  |  |  | - |  |
| Dr. Yuan Liu |  |  | - |  |  |  | - |  |
| Zhiyuan Ran |  |  | - |  |  |  | - |  |
| Dr. Honggang Teng |  |  | - |  |  |  | - |  |
| All executive officers and directors as a group |  |  | 313,638 |  |  |  | 0.8 |  |
| **Principal Shareholders:** |  |  |  |  |  |  |  |  |
| Crystal Peak Investment Inc.(3) |  |  | 21,021,332 |  |  |  | 51.0 |  |
| Fung Ching Wong / Apex Prospect Limited(4) |  |  | 9,836,010 |  |  |  | 23.9 |  |
| Yi Zhang and his affiliated entities(5) |  |  | 4,908,919 |  |  |  | 11.9 |  |

|  |  |  |
| --- | --- | --- |
|  | Notes: |  |

|  |  |  |
| --- | --- | --- |
|  | (1) | The business address of our directors and executive officers is Building No. 2, 38 Yongda Road, Daxing Biomedical Industry Park, Daxing District, Beijing, PRC. |

|  |  |  |
| --- | --- | --- |
|  | (2) | Represents (1) 180,278 ordinary shares held by Mountainview Investment Holdings LLC, a limited liability company incorporated under the laws of the State of Delaware and wholly-controlled by Mr. Hui Shao; and (2) 133,360 ordinary shares directly held by Mr. Hui Shao. The business address of Mountainview Investment Holdings LLC is 8 The Green, Suite B, Dover, Delaware 19901, USA. |

|  |  |  |
| --- | --- | --- |
|  | (3) | Represents 21,021,332 ordinary shares owned by Crystal Peak Investments Inc (“Crystal Peak”). Ms. Huaqin Xue (“Ms. Xue”) currently exercises voting and dispositive control over these ordinary shares. Crystal Peak and Ms. Xue may each be deemed to have shared voting and dispositive power over all of these shares. Information set forth above is based upon Ms. Xue’s Schedule 13D filed with the SEC on July 22, 2025. The principal business address of Crystal is Kingston Chambers, PO Box 173, Road Town, Tortola, British Virgin Islands. |

|  |  |  |
| --- | --- | --- |
|  | (4) | Represents 9,836,010 ordinary shares owned by Apex Prospect Limited (“Apex”). Ms. Fung Ching Wong (“Ms. Wong”) currently exercises voting and dispositive control over these ordinary shares. Apex and Ms. Wong may each be deemed to have shared voting and dispositive power over all of these shares. Information set forth above is based upon Ms. Wong’s Schedule 13D filed with the SEC on February 14, 2024, as amended on July 15, 2025. The principal business address of Apex is Floor 4, Willow House, Cricket Square, P O Box 2804, Grand Cayman KY1-1112, Cayman Islands. |

|  |  |  |
| --- | --- | --- |
|  | (5) | Represents (1) 3,897,200 ordinary shares held by All Brilliance Investments Limited, a limited liability company incorporated under the laws of British Virgin Islands and being wholly-controlled by Mr. Yi Zhang; (2) 457,150 ordinary shares held by Hopeful World Company Limited, a limited liability company incorporated under the laws of British Virgin Islands and being wholly-controlled by Ms. Rui Mi, the spouse of Mr. Yi Zhang; (3) 243,575 ordinary shares held by Acton Town International Limited, a limited liability company incorporated under the laws of British Virgin Islands and being held wholly-controlled by Ms. Nan Zhang, a daughter of Mr. Yi Zhang; (4) 243,575 ordinary shares held by Apex Pride Global Limited, a limited liability company incorporated under the laws of British Virgin Islands and wholly-controlled by Ms. Xu Zhang, a daughter of Mr. Yi Zhang; (5) 62,919 ordinary shares directly held by Mr. Yi Zhang; (6) 1,334 ordinary shares directly held by Ms. Nan Zhang; and (7) 3,166 ordinary shares directly held by Ms. Xu Zhang. Mr. Yi Zhang and his aforementioned affiliates have entered into an acting-in-concert agreement to act in concert with Mr. Yi Zhang. Information set forth above is based upon Mr. Yi Zhang and his affiliated entities’ Amendment No.1 to Schedule 13D filed with the SEC on February 16, 2024. The principal business addresses of All Brilliance Investments Limited and Hopeful World Company Limited are Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands. The principal business addresses of Acton Town International and Apex Pride Global Limited are Portcullis TrustNet Chambers, P.O. Box 3444, Road Town, Tortola, British Virgin Islands. |

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| --- | --- | --- |
|  | **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** |

See “Item 6. Directors, Senior Management and Employees—E. Share Ownership.”

|  |  |  |
| --- | --- | --- |
|  | **B.** | **Related Party Transactions** |

**Employment Agreements and Indemnification Agreements**

See “Item 6. Directors, Senior Management and Employees—B. Compensation—Employment Agreements and Indemnification Agreements.”

***Share Incentive Plans***

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

***Other Related Party Transactions***

In July 2023, LakeShore Group spent US$20,000 to purchase a vehicle from Rui Mi, spouse of Mr. Yi Zhang that was subsequently purchased back by Rui Mi in March 2024.

In fiscal year 2025, LakeShore Group purchased service and property, plant and equipment of RMB0.3 million and RMB0.1 million from Beijing Yisheng Xingye Technology Co., Ltd. As of March 31, 2025, LakeShore Group has repaid it fully.

In fiscal year 2025, LakeShore Group purchased service of RMB1.8 million from HaiSong Zhiyuan (Beijing) Management Consulting Co., Ltd. As of March 31, 2025, the balance of the accrued expenses and other liabilities was RMB0.7 million.

In fiscal 2025, LakeShore Group borrowed RMB3.6 million with interest at 5.0% from Apex Prospect Limited, accrued interest RMB0.01 million. As of March 31, 2025, the balance of bank loans and other borrowings - current and accrued expenses and other liabilities were RMB3.6 million and RMB0.01 million.

In fiscal year 2025, LakeShore Group borrowed RMB311.4 million with interest at 5.0% from Beijing Huarui Jingkai Real Estate Co., Ltd, which has accrued interest of RMB7.6 million. LakeShore Group has paid RMB4.1 million. As of March 31, 2025, the balance of the bank loans and other borrowing – current and accrued expenses and other liabilities were RMB311.4 million and RMB3.5 million, respectively.

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|  |  |  |
| --- | --- | --- |
|  | **C.** | **Interests of Experts and Counsel** |

Not applicable.

**ITEM 8. FINANCIAL INFORMATION**

|  |  |  |
| --- | --- | --- |
|  | **A.** | **Consolidated Statements and Other Financial Information** |

We have appended consolidated financial statements filed as part of this Annual Report.

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| --- | --- | --- |
|  | **B.** | **Significant Changes** |

We have not experienced any significant changes since the date of our audited consolidated financial statements included in this Annual Report.

**ITEM 9. THE OFFER AND LISTING**

|  |  |  |
| --- | --- | --- |
|  | **A.** | **Offering and Listing Details** |

Our ordinary shares and Warrants currently trade on Nasdaq under the symbols “LSB” and “LSBPW,” respectively.

|  |  |  |
| --- | --- | --- |
|  | **B.** | **Plan of Distribution** |

Not applicable.

|  |  |  |
| --- | --- | --- |
|  | **C.** | **Markets** |

See “—A. Offering and Listing Details.”

|  |  |  |
| --- | --- | --- |
|  | **D.** | **Selling Shareholders** |

Not applicable.

|  |  |  |
| --- | --- | --- |
|  | **E.** | **Dilution** |

Not applicable.

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| --- | --- | --- |
|  | **F.** | **Expenses of the Issue** |

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

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| --- | --- | --- |
|  | **A.** | **Share Capital** |

Not applicable.

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| --- | --- | --- |
|  | **B.** | **Memorandum and Articles of Association** |

The following are summaries of material provisions of our currently effective second amended and restated memorandum and articles of association, hereinafter referred to as the “Articles”, and of the Companies Act (As Revised) of the Cayman Islands, which we refer to as the “Companies Act” below, insofar as they relate to the material terms of our ordinary shares.

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**Board of Directors**

See “Item 6. Directors, Senior Management and Employees—C. Board Practices.”

**Ordinary Shares**

***General***

Holders of ordinary shares have the same rights. All of the ordinary shares are fully paid and non-assessable. Our Shareholders who are non-residents of the Cayman Islands may freely hold and transfer their ordinary shares.

***Dividends***

The holders of ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our board of directors. The Articles provide that our directors may, before recommending or declaring any dividend, set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall, in the absolute discretion of the directors, be applicable for meeting contingencies or for equalizing dividends or for any other purpose to which those funds may be properly applied. Under the laws of the Cayman Islands, we may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in us being unable to pay its debts as they fall due in the ordinary course of business.

***Voting Rights***

In respect of all matters subject to a shareholders’ vote, each ordinary share is entitled to one vote. Voting at any meeting of shareholders is by show of hands unless a poll is (before or on the declaration of the result of the show of hands) demanded. A poll may be demanded by the chairperson of such meeting or any one or more shareholders holding not less than ten per cent (10%) of the votes attaching to the ordinary shares present in person or by proxy and entitled to vote. An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes cast attaching to the issued and outstanding ordinary shares at a meeting and includes a unanimous written resolution. A special resolution will be required for important matters such as a change of name, reducing the share capital or making changes to the Articles.

***Transfer of Ordinary Shares***

Subject to the restrictions contained in the 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 there is 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 shares to which it relates (if any) 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 share is to be transferred does not exceed four; or |

|  |  |  |
| --- | --- | --- |
|  | ● | a fee of such maximum sum as Nasdaq may determine to be payable, or such lesser sum as our board of directors may from time to time require, is paid to us in respect thereof. |

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If our directors refuse to register a transfer, they shall, within three calendar months after the date on which the instrument of transfer was lodged with us, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on ten calendar days’ notice being given by advertisement in such one or more newspapers, by electronic means or by any other means in accordance with Nasdaq Rules, be suspended and the register of members closed at such times and for such periods as the board of directors may, in their absolute discretion, from time to time determine, provided, always that the registration of transfers shall not be suspended nor the register of members closed for more than 30 days in any calendar year.

***Liquidation***

On a return of capital on winding-up, and the assets available for distribution among the holders of ordinary shares shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the ordinary shares held by them at the commencement of the winding up subject to a deduction from those ordinary shares in respect of which there are monies due, of all monies payable to us for unpaid calls or otherwise. If the assets available for distribution are insufficient to repay all of the whole of the share capital, such assets shall be distributed so that as nearly as may be, the losses shall be borne by our shareholders in proportion to the par value of the ordinary shares held by them.

***Calls on Ordinary Shares and Forfeiture of Ordinary Shares***

Our directors may from time to time make calls upon shareholders for any amounts unpaid on their ordinary shares (subject to receiving at least fourteen calendar days’ notice specifying the time or times of payment). The sum called in respect of ordinary shares that remain unpaid are, after a notice period given pursuant to the provision of the Articles, subject to forfeiture.

***Redemption of Ordinary Shares***

Subject to the provisions of the Cayman Islands Companies Act, we may issue shares that are to be redeemed or are liable to be redeemed at the option of the shareholder or us. The redemption of such shares will be effected in such manner and upon such other terms as we may, by either resolution of our board of directors or special resolution of our shareholders, determine before the issue of such shares. We may also repurchase any ordinary shares (including any redeemable shares) on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders.

Under the Cayman Islands Companies Act, the redemption or repurchase of any share may be paid out of the 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 (i) unless it is fully paid up, (ii) if such redemption or repurchase would result in there being no shares issued and outstanding, or (iii) if the company has commenced liquidation. In addition, our directors may accept the surrender of any fully paid share for no consideration.

***Variation of Rights of Shares***

All or any of the special rights attached to any class of shares may, subject to the provisions of the Cayman Islands Companies Act, be materially adversely varied with the consent in writing of the holders of not less than two-thirds of the issued shares of that class, or with the sanction of a special resolution passed by the holders of shares of the class present in person or by proxy at a separate general meeting of the holders of the shares of that class. 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 materially adversely varied by, inter alia, the creation, allotment or issue of further shares ranking pari passu with or subsequent to such existing class of shares. The rights of the holders of ordinary shares shall not be deemed to be materially adversely varied by the creation or issue of shares with preferred or other rights including, without limitation, the creation of shares with enhanced or weighted voting rights.

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***General Meetings of Shareholders***

Shareholders’ meetings may be convened by our chairperson or a majority of our board of directors (acting by a resolution of the board). Advance notice of at least seven (7) calendar days is required for the convening of its annual general shareholders’ meeting and any other general meeting of its shareholders, provided that a general meeting of the Company shall be deemed to have been duly convened if it is so agreed by two-thirds of the shareholders (or their proxies) having a right to attend and vote at the meeting, present at the meeting.

The Companies Act provides shareholders with only limited rights to requisition a general meeting and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company’s articles of association. The Articles provide that upon the requisition of shareholders representing in aggregate not less than 10% of all votes attaching to our issued and outstanding shares entitled to vote at general meetings as at the date of the deposit of the requisition, our board is obliged to convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. However, the 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.

***Voting Rights Attaching to the Shares.***

Subject to any rights and restrictions for the time being attached to any Share, on a show of hands every shareholder present in person and every person representing a shareholder by proxy shall, at a shareholders’ meeting, each have one vote and on a poll every shareholder and every person representing a shareholder by proxy shall have one vote for each Share of which he or the person represented by proxy is the holder.

***Inspection of Books and Records***

Our board of directors will determine whether, to what extent, at what times and places and under what conditions or articles our accounts and books will be open to the inspection by our shareholders, and none of our shareholder (not being our director) will otherwise have any right of inspecting any of our account or book or document except as required by the Cayman Islands Companies Act, authorized by our board of directors or by an ordinary resolution of our shareholders. 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 (except for our memorandum and articles of association, our register of mortgages and charges and special resolutions of our shareholders).

***Changes in Capital***

We may from time to time by ordinary resolution:

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|  | ● | increase our share capital by such sum, to be divided into shares of such amount, as the resolution will prescribe; |

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|  | ● | consolidate and divide all or any of its share capital into shares of a larger amount than existing shares; |

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|  | ● | sub-divide its existing shares or any of them into shares of a smaller amount; provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share will be the same as it was in case of the share from which the reduced share is derived; or |

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|  | ● | cancel any shares that at the date of the passing of the resolution have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the shares so cancelled. |

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We may by special resolution, subject to any confirmation or consent required by the Cayman Islands Companies Act, reduce our share capital or any capital redemption reserve in any manner permitted by law.

***Warrants***

Upon the consummation of the Business Combination, each Warrant outstanding immediately prior had ceased to be a warrant with respect to Summit Public Shares and was assumed by LakeShore Biopharma and converted into a LakeShore Biopharma Warrant entitling the holder thereof to purchase such number of Ordinary Share on a one-on-one basis. After the merger with Summit, the Company accounted for the 10,750,000 public warrants as equity and 6,000,000 private warrants as liabilities. LakeShore Biopharma completed a 1-for-10 reverse stock split in October 2024, each warrant became exercisable for 0.1 share of common stock.

***Registered Office and Objects***

Our registered office in the Cayman Islands is located at the offices of Maples Corporate Services Limited, PO Box 309, Ugland House, Grand Cayman, KY1-1104, Grand Cayman KY1-1104, Cayman Islands, or at such other location within the Cayman Islands as our directors may from time to time decide. The objects for which our company is established are unrestricted and we have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

***Differences in Corporate Law***

The Companies Act is derived, to a large extent, from the older Companies Acts of England but does not follow recent English statutory enactments and accordingly there are significant differences between the Companies Act and the current Companies Act of England. In addition, the Companies Act differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

*Mergers and Similar Arrangements.* The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (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 consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (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 written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose, a company is a “parent” of a subsidiary if it holds issued shares that together represent at least ninety percent (90%) of the votes at a general meeting of the subsidiary.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

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Save in certain limited circumstances, a shareholder of a Cayman constituent company who dissents from the merger or consolidation is entitled to payment of the fair value of his shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) upon dissenting to the merger or consolidation, provide the dissenting shareholder complies strictly with the procedures set out in the Companies Act. The exercise of dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

Separate from the statutory provisions relating to mergers and consolidations, the Companies Act also contains statutory provisions that facilitate the reconstruction and amalgamation of companies by way of schemes of arrangement, provided that the arrangement is approved by (1) three fourths in value of the shareholders or class of shareholders, as the case may be, or (2) a majority in number representing three fourths in value of the creditors or each class of creditors, as the case may be, with whom the arrangement is to be made, that are, in each case, present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

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|  | ● | the statutory provisions as to the required majority vote have been met; |

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|  | ● | 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; |

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|  | ● | the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and |

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|  | ● | the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act. |

The Companies Act also contains a statutory power of compulsory acquisition which may facilitate the “squeeze out” of dissentient minority shareholder upon a tender offer. When a tender offer is made and accepted by holders of 90.0% of the shares affected within four months, the offeror may, within a two-month period commencing on the expiration of such four-month period, require the holders of the remaining shares to transfer such shares to the offeror on the terms of the offer. An objection can be made to the Grand Court, but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted in accordance with the foregoing statutory procedures, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

*Shareholders’ suits.* In principle, we will normally be the proper plaintiff and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands courts can be expected to follow English case law precedents and apply the common law principles (namely the rule in *Foss v. Harbottle* and the exceptions thereto) which permit a minority shareholder to commence a class action against, or derivative actions in the name of, the company to challenge:

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|  | ● | an act which is ultra vires or illegal and is therefore incapable of ratification by the shareholders; |

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|  | ● | an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company; and |

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|  | ● | an action which requires a resolution with a qualified (or special) majority which has not been obtained. |

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*Indemnification of directors and executive officers and limitation of liability.* Cayman Islands law does not limit the extent to which a company’s memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our second memorandum and articles of association provides that our directors and officers and the personal representatives of the same shall be indemnified against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained in or about the conduct of the company’s business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of their duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning the Company or its affairs in any court whether in the Cayman Islands or elsewhere, provided that the indemnity shall not extend to any matter in respect of any willful default, fraud or dishonesty which may attach to any of said persons.

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 the Articles.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for 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 as a matter of United States law.

*Directors’ Fiduciary Duties.* Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a 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 exercise the skill they actually possess and such care and diligence that a reasonably prudent person would exercise in comparable circumstances. 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. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended and restated from time to time.

*Shareholder action by written consent.* Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. The Companies Act and the Articles provide that shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

*Shareholder proposals.* Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

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The Companies Act provides shareholders with only limited rights to requisition a general meeting and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company’s articles of association. The Articles allow our shareholders holding in aggregate not less than 10% of all votes attaching to all issued and outstanding shares of our company entitled to vote at general meetings to requisition a shareholder’s meeting, in which case our directors shall convene an extraordinary general meeting. Other than this right to requisition a shareholders’ meeting, the Articles do not provide our shareholders other right to put proposal before annual general meetings or extraordinary general meetings not called by such shareholders. As an exempted Cayman Islands company, we are not obligated by law to call shareholders’ annual general meetings.

*Cumulative voting.* Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation’s certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled on a single director, which increases the shareholder’s voting power with respect to electing such director. There are no prohibitions in relation to cumulative voting under the Companies Act but the Articles do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

*Removal of directors.* Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under the Articles, subject to certain restrictions as contained therein, directors may be removed with or without cause, by an ordinary resolution of our shareholders. An appointment of a director may be on terms that the director shall automatically retire from office (unless he has sooner vacated office) at the next or a subsequent annual general meeting or upon any specified event or after any specified period in a written agreement between the company and the director, if any; but no such term shall be implied in the absence of express provision. A director shall hold office until the expiration of his or her term or his or her successor shall have been elected and qualified, or until his or her office is otherwise vacated. 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) resigns his office by notice in writing to the company; (4) is removed from office by notice addressed to them at their last known address and signed by all their co-directors (not being less than two in number); or (5) is removed from office pursuant to any other provisions of the Articles.

*Transactions with interested shareholders.* The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an “interested shareholder” for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target’s outstanding voting share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target’s board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, the directors of the company are required to comply with the fiduciary duties which they owe to the company under Cayman Islands law, including the duty to ensure that, in their opinion, any such transactions entered into are bona fide in the best interests of the company, and are entered into for a proper corporate purpose and not with the effect of constituting a fraud on the minority shareholders.

*Restructuring.* A company may present a petition to the Grand Court for the appointment of a restructuring officer on the grounds that the company: (1) is or is likely to become unable to pay its debts; and (2) intends to present a compromise or arrangement to its creditors (or classes thereof) either pursuant to the Companies Act, the law of a foreign country or by way of a consensual restructuring.

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The Grand Court may, among other things, make an order appointing a restructuring officer upon hearing of such petition, with such powers and to carry out such functions as the court may order. At any time (1) after the presentation of a petition for the appointment of a restructuring officer but before an order for the appointment of a restructuring officer has been made, and (2) when an order for the appointment of a restructuring officer is made, until such order has been discharged, no suit, action or other proceedings (other than criminal proceedings) shall be proceeded with or commenced against the company, no resolution to wind up the company shall be passed, and no winding up petition may be presented against the company, except with the leave of the court. However, notwithstanding the presentation of a petition for the appointment of a restructuring officer or the appointment of a restructuring officer, a creditor who has security over the whole or part of the assets of the company is entitled to enforce the security without the leave of the court and without reference to the restructuring officer appointed.

*Dissolution; winding up.* Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation’s outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so.

*Variations of rights of shares.* Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and the Articles, if at any time, our share capital is divided into different classes of shares, the rights attached to any class of shares (unless otherwise provided by the terms of issue of the shares of that class) may be materially and adversely varied with the consent in writing of the holders of two-thirds of the issued shares of that class or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be materially adversely varied by, inter alia, the creation, allotment or issue of further shares ranking pari passu with or subsequent to them or the redemption or purchase of any shares of any class by the company. The rights of the holders of the shares shall not be deemed to be materially adversely varied by the creation or issue of shares with preferred or other rights including, without limitation, the creation of shares with enhanced or weighted voting rights.

*Amendment of governing documents.* Under the Delaware General Corporation Law, a corporation’s governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under Cayman Islands law, the Articles may only be amended by a special resolution of our shareholders.

*Rights of non-resident or foreign shareholders.* There are no limitations imposed by the Articles on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in the Articles that require our company to disclose shareholder ownership above any particular ownership threshold.

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|  | ***C.*** | **Material Contracts** |

*The following descriptions of the material provisions of the referenced agreements do not purport to be complete and are subject to, and qualified in their entirety by reference to the agreements which have been filed as exhibits to this Annual Report.*

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**Share Purchase Agreement with Apex Prospect Limited**

On February 7, 2024, the Company entered into a share purchase agreement with Apex Prospect Limited (“Apex”), a Cayman Islands exempted company, pursuant to which Apex purchased 95,269,762 ordinary shares from the Company at price of US$0.41986 per share for a total purchase price of US$40 million.

**Financing Lease Agreements with Zhonghao Financial Leasing (Tianjin) Co., Ltd.**

On April 1, 2025, the Company has, through its subsidiary, Liaoning Yisheng Biopharma Co., Ltd. (the “Lessee”), entered into two financing lease agreements (the “Financing Lease Agreements”) with Zhonghao Financial Leasing (Tianjin) Co., Ltd. (the “Lessor”). Pursuant to the Financing Lease Agreements, (1) the Lessee transferred ownership of certain self-owned assets (the “Leased Assets”) to the Lessor for a total consideration of RMB110 million (the “Lease Principal”), covering RMB80 million and RMB30 million under the two agreements, respectively, and (2) concurrently leased back the Leased Assets from the Lessor for continued operational use. The lease term concludes on March 31, 2026 (the “Maturity Date”), with interest accruing at an annual rate of 5% on the Lease Principal (the “Lease Interest”). The total outstanding Lease Principal and accrued Lease Interest are payable in full as a single lump-sum payment on the Maturity Date. Upon the Maturity Date, the Lessee retains the right to repurchase the Leased Assets at a nominal price of RMB100, provided that (i) the Lessee has not defaulted under the Financing Lease Agreements and (ii) all payment obligations have been satisfied in full. The Financing Lease Agreement are filed as Exhibits 4.6.1 and 4.6.2 to this Annual Report.

**Share and Warrant Purchase Agreement with Crystal Peak Investment Inc.**

On July 8, 2025, the Company entered into a Share and Warrant Purchase Agreement (the “Purchase Agreement”) with Crystal Peak Investment Inc. (“Crystal Peak”), a private limited liability company incorporated under the laws of the British Virgin Islands. Pursuant to the agreement, the Company issued and sold 16,987,542 ordinary shares, each with a par value of US$0.0002, at a price of US$0.883 per share, together with 16,987,542 warrants. Each warrant entitles Crystal to purchase one ordinary share at an exercise price of US$1.079 at any time during a 36-month period, in a private placement totaling US$15 million. Additionally, 4,033,790 ordinary shares were issued on July 11, 2025, following the fully cashless exercise of warrants. The Share and Warrant Purchase Agreement is filed as Exhibit 4.3 to this Annual Report.

Other than in the ordinary course of business and other than those described above in this section and in “Item 4. Information on the Company”, “Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions” or elsewhere in this Annual Report, we have not entered into any material contract during the two years immediately preceding the date of this Annual Report.

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|  | **D.** | **Exchange Controls** |

See “Item 4. Information on the Company—B. Business Overview—Regulations.”

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|  | **E.** | **Taxation** |

The following summary of Cayman Islands, the PRC and United States federal income tax consequences of an investment in our ordinary shares or warrants is based upon laws and relevant interpretations thereof in effect as of the date of this Annual Report, all of which are subject to change. This summary does not deal with all possible tax consequences relating to an investment in our ordinary shares, such as the tax consequences under state, local and other tax laws, or tax laws of jurisdictions other than the Cayman Islands, the PRC and the United States. To the extent that the discussion relates to matters of Cayman Islands tax law, it represents the opinion of Maples and Calder (Hong Kong) LLP, our counsel as to Cayman Islands law, and to the extent it relates to summary or description of PRC tax law, it represents the opinion of Jingtian & Gongcheng, our counsel as to PRC law.

***Cayman Islands Taxation***

The following is a discussion of certain Cayman Islands income tax consequences of an investment in the ordinary shares. The discussion is a general summary of present law, which is subject to prospective and retroactive change. It is not intended as tax advice, does not consider any investor’s particular circumstances, and does not consider tax consequences other than those arising under Cayman Islands law.

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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 interest and principal or a dividend or capital to any holder of our ordinary shares, as the case may be, nor will gains derived from the disposal of our ordinary shares be subject to Cayman Islands income or corporation tax.

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 applicable to payments to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability and have received an undertaking from the Governor in Cabinet of the Cayman Islands in substantially the following form:

*The Tax Concessions Law  
Undertaking as to Tax Concessions*

In accordance with the Tax Concessions Act (As Revised) of the Cayman Islands, the Cabinet Office undertakes with us

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|  | (a) | That no Law which is hereafter enacted in the Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to us or our operations; and |

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|  | (b) | In addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable: |

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|  | (i) | on or in respect of the shares, debentures or other obligations of us; or |

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|  | (ii) | by way of the withholding in whole or part, of any relevant payment as defined in the Tax Concessions Act (As Revised). |

These concessions shall be for a period of TWENTY years from the October 4, 2022.

***PRC Taxation***

Under the EIT Law and its implementation rules, an enterprise established outside of China with a “de facto management body” within China 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 the body that exercises full and substantial control over and overall management of the business, productions, personnel, accounts and properties of an enterprise. In April 2009, SAT issued the 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 the Circular 82 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 82 may reflect the general position of SAT on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. According to the 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 to perform their duties 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.

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We do not believe that we, a Cayman Islands holding company meets all of the conditions above. As a holding company, our accounting books and records and resolutions are located or maintained outside China. For the same reasons, we believe other our subsidiaries 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 ours.

Jingtian & Gongcheng, our legal counsel as to the PRC law, advised us that if the PRC tax authorities determine that we, a Cayman Islands holding company, are a PRC resident enterprise for enterprise income tax purposes, we may be required to withhold a 10% withholding tax from dividends we pay to our security holders that are non-PRC resident enterprises, including the holders of the ordinary shares and warrants. In addition, non-PRC resident enterprise shareholders (including the holders of ordinary shares and warrants) may be subject to a 10% PRC tax on gains realized on the sale or other disposition of such securities, if such income is treated as sourced from within China. It is unclear whether our non-PRC individual shareholders (including the holders of ordinary shares and warrants) would be subject to any PRC tax on dividends or gains obtained by such non-PRC individual shareholders in the event we are determined to be a PRC resident enterprise. 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. However, it is also unclear whether non-PRC shareholders of LakeShore Biopharma would be able to claim the benefits of any tax treaties between their country of tax residence and China in the event that LakeShore Biopharma is treated as a PRC resident enterprise.

Provided we are not deemed to be a PRC resident enterprise, holders of our securities (including ordinary shares and warrants) who are not PRC residents will not be subject to PRC income tax on dividends distributed by it or gains realized from the sale or other disposition of its securities. However, under SAT Bulletin 7, where a non-resident enterprise conducts an “indirect transfer” by transferring taxable assets, including, in particular, equity interests in a PRC resident enterprise, indirectly by disposing of the equity interests of an overseas holding company, the non-resident enterprise, being the transferor, or the transferee or the PRC entity of which the equity interests are transferred may report to the relevant tax authority such indirect transfer. Using a “substance over form” principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at 10% for the transfer of equity interests in a PRC resident enterprise. We and our non-PRC resident investors may be at risk of being required to file a return and being taxed under SAT Bulletin 7, and we may be required to expend valuable resources to comply with SAT Bulletin 7, or to establish that it should not be taxed thereunder. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China.”

***United States Federal Income Tax Considerations***

The following discussion is a summary of U.S. federal income tax considerations generally applicable to an investment in our ordinary shares by a U.S. Holder (as defined below). This discussion is based on the federal income tax laws of the U.S. as of the date of this Annual Report, including the United States Internal Revenue Code of 1986, as amended, (the “Code”), existing and proposed U.S. Treasury Regulations promulgated thereunder, judicial authority, published administrative positions of the U.S. Internal Revenue Service (the “IRS”), and other applicable authorities, all as of the date of this Annual Report. All of the foregoing authorities are subject to change, which change could apply retroactively and could significantly affect the tax consequences described below. We have not sought, nor do we intend to seek, any ruling from the IRS with respect to the U.S. federal income tax consequences described below, and there can be no assurance that the IRS will not take, and a court would sustain, a contrary position. This discussion, moreover, does not address the U.S. federal estate, gift, Medicare, and alternative minimum tax or other non-income tax considerations, or any state, local or non-U.S. tax considerations, relating to an investment in our ordinary shares.

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Except as specifically described below, this discussion does not address any tax consequences or reporting obligations that may be applicable to persons to the extent such tax consequences or reporting obligations arise from holding our ordinary shares through a bank, financial institution or other entity, or a branch thereof, located, organized or resident outside the United States and does not describe any tax considerations arising in respect of the Foreign Account Tax Compliance Act (“FATCA”).

This discussion applies only to a U.S. Holder (as defined below) that holds our ordinary shares as capital assets for U.S. federal income tax purposes (generally, property held for investment). The discussion neither addresses the tax consequences to any particular investor nor describes all of the tax consequences applicable to persons in special tax situations, such as:

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|  | ● | banks and certain other financial institutions; |

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|  | ● | insurance companies; |

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| --- | --- | --- |
|  | ● | regulated investment companies; |

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| --- | --- | --- |
|  | ● | real estate investment trusts; |

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| --- | --- | --- |
|  | ● | controlled foreign corporations; |

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|  | ● | “qualified foreign pension funds” (within the meaning of Section 897(l)(2) of the Code) and entities whose interests are held by qualified foreign pension funds; |

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| --- | --- | --- |
|  | ● | dealers, brokers or traders in securities, commodities or foreign currencies; |

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|  | ● | persons that use or are required to use a mark-to-market method of accounting; |

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| --- | --- | --- |
|  | ● | accrual method taxpayers that file applicable financial statements as described in Section 451(b) of the Code; |

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|  | ● | certain former citizens or residents of the United States subject to Section 877 of the Code; |

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|  | ● | entities subject to the United States anti-inversion rules; |

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| --- | --- | --- |
|  | ● | tax-exempt organizations and entities; |

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| --- | --- | --- |
|  | ● | individual retirement accounts and Roth IRAs; |

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| --- | --- | --- |
|  | ● | S corporations; |

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|  | ● | PFICs or their stockholders; |

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|  | ● | persons whose functional currency is other than the United States dollar; |

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| --- | --- | --- |
|  | ● | persons holding ordinary shares as part of a straddle, hedging, conversion or integrated transaction; |

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|  | ● | persons that actually or constructively own ordinary shares representing 5% or more of our total voting power or value; |

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|  | ● | persons who acquired ordinary shares pursuant to the exercise of an employee stock option or otherwise as compensation; |

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|  | ● | partnerships or other pass-through entities, or persons holding ordinary shares through such entities; |

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|  | ● | persons required to accelerate the recognition of any item of gross income with respect to our ordinary shares as a result of such income being recognized on an applicable financial statement; or |

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| --- | --- | --- |
|  | ● | non-U.S. Holders. |

This discussion does not consider the U.S. federal income tax treatment of partnerships or other pass-through entities or arrangements or persons that hold our ordinary shares through such entities. If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the tax treatment of a partner in the partnership generally will depend upon the status of the partner and the activities of the partner and the partnership. A partnership or partner in a partnership holding our ordinary shares should consult its tax advisors regarding the tax consequences of investing in and holding our ordinary shares.

**THE FOLLOWING DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT A SUBSTITUTE FOR CAREFUL TAX PLANNING AND ADVICE. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE UNITED STATES FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE UNITED STATES FEDERAL ESTATE OR GIFT TAX LAWS OR THE LAWS OF ANY STATE, LOCAL OR NON-UNITED STATES TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.**

For purposes of the discussion below, a “U.S. Holder” is a beneficial owner of our ordinary shares that is, for United States federal income tax purposes:

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|  | ● | an individual who is a citizen or resident of the United States; |

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|  | ● | a corporation (or other entity that is treated as a corporation for U.S. federal income tax purposes) that is created or organized (or treated as created or organized) in or under the laws of the U.S. or any state thereof or the District of Columbia; |

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|  | ● | an estate, the income of which is subject to United States federal income taxation regardless of its source; or |

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|  | ● | a trust if (i) a U.S. court can exercise primary supervision over the administration of such trust and one or more U.S. persons (within the meaning of the Code) have the authority to control all substantial decisions of the trust or (ii) it has a valid election in place to be treated as a U.S. person. |

**Dividends and Other Distributions on Our Ordinary Shares**

Subject to the PFIC rules discussed below, the gross amount of any distributions we make to you with respect to our ordinary shares (without reduction for any amounts withheld) generally will be includible in a U.S. Holder’s gross income as foreign source dividend income on the date of receipt by such U.S. Holder, but only to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Any such dividends will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from other U.S. corporations. To the extent that the amount of the distribution exceeds our current and accumulated earnings and profits (as determined under U.S. federal income tax principles), such excess amount will be treated first as a tax-free return of a U.S. Holder’s tax basis in its ordinary shares, and then, to the extent such excess amount exceeds such U.S. Holder’s tax basis in its ordinary shares, as capital gain. However, we currently do not, and we do not intend to, calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that any distribution will generally be reported as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may be taxed at the lower capital gains rate applicable to “qualified dividend income,” provided that (1) our ordinary shares are readily tradable on an established securities market in the United States or we are eligible for the benefits of a qualifying income tax treaty with the United States, (2) we are neither a PFIC nor treated as such with respect to you (as discussed below) for the taxable year in which the dividend is paid or the preceding taxable year, and (3) the ordinary shares are held for a holding period of more than 60 days during the 121-day period beginning 60 days before the ex-dividend date. Ordinary shares are generally considered for the purpose of clause (1) above to be readily tradable on an established securities market in the United States if they are listed on Nasdaq, as our ordinary shares currently are. If we are treated as a “resident enterprise” for PRC tax purposes, we may be eligible for the benefits of the income tax treaty between the U.S. and the PRC (the “Treaty”). U.S. Holders should consult their own tax advisors regarding the availability of the lower capital gains rate applicable to qualified dividend income for any dividends paid with respect to our ordinary shares.

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Any non-U.S. withholding tax (including any PRC withholding tax paid (or deemed paid) by a United States. Holder at the rate applicable to such holder may be eligible for foreign tax credits (or deduction in lieu of such credits) for U.S. federal income tax purposes, subject to applicable limitations. Any dividends will constitute foreign source income for foreign tax credit limitation purposes. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by the reduced tax rate applicable to qualified dividend income and divided by the highest tax rate normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, any dividends distributed by us with respect to ordinary shares will generally constitute “passive category income.”

The rules relating to the determination of the foreign tax credit are complex and U.S. Holders should consult their tax advisors to determine whether and to what extent a credit would be available in their particular circumstances, including the effects of any applicable income tax treaties.

**Sale, Exchange, Redemption or Other Taxable Disposition of Our Ordinary Shares**

Subject to the PFIC rules discussed below, upon a sale or other taxable disposition of our ordinary shares, a U.S. Holder will generally recognize capital gain or loss. The amount of gain or loss recognized will generally be equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. Holder’s adjusted tax basis in our ordinary shares.

Under tax law currently in effect long-term capital gains recognized by non-corporate U.S. Holders are generally subject to United States federal income tax at a reduced rate of tax. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder’s holding period for the ordinary shares exceeds one year. The deductibility of capital losses is subject to various limitations.

Any gain or loss that a U.S. Holder recognizes on a disposition of our ordinary shares generally will be treated as United States-source income or loss for foreign tax credit limitation purposes. However, if we are treated as a PRC resident enterprise for PRC tax purposes and PRC tax is imposed on gain from the disposition of our ordinary shares, then a U.S. Holder that is eligible for the benefits of the Treaty may elect to treat the gain as PRC-source income for foreign tax credit purposes. If such an election is made, the gain so treated will be treated as a separate class or “basket” of income for foreign tax credit purposes. You should consult your tax advisors regarding the proper treatment of gain or loss, as well as the availability of a foreign tax credit, in your particular circumstances.

**Passive Foreign Investment Company**

Certain adverse U.S. federal income tax consequences could apply to a U.S. Holder if we, or any of our subsidiaries, are treated as a PFIC for any taxable year during which the U.S. Holder holds our ordinary shares.

A non-U.S. corporation will be classified as a PFIC for any taxable year (a) if at least 75% of its gross income consists of passive income, such as dividends, interest, rents and royalties (except for rents and royalties earned in the active conduct of a trade or business), and gains on the disposition of property that produces such income, or (b) if at least 50% of the average value of its assets (determined on the basis of a quarterly average) is attributable to assets that produce, or are held for the production of, passive income (including for this purpose its pro rata share of the gross income and assets of any entity in which it is considered to own at least 25% of the interest, by value).

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Based on our income, assets, and operations and our subsidiaries, we do not believe we were a PFIC in the taxable year ended March 31, 2025, although there can be no assurance that the IRS or a court will not challenge our position in this regard. Whether we or any of our subsidiaries is treated as a PFIC for U.S. federal income tax purposes is a factual determination that must be made annually at the close of each taxable year and, thus, is subject to significant uncertainty. Among other factors, fluctuations in the market price of the ordinary shares and how quickly we use liquid assets and cash may influence whether we or any of our subsidiaries is treated as PFIC. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for any future taxable year, and no opinion of counsel has or will be provided regarding the classification of us as a PFIC. Accordingly, there can be no assurance that we or any of our subsidiaries will not be treated as a PFIC for any taxable year. Moreover, we do not expect to provide a PFIC annual information statement for the taxable year ending March 31, 2025 or going forward.

If we were characterized as a PFIC for any taxable year, U.S. Holders of our ordinary shares would suffer adverse tax consequences. These consequences may include having gains realized on the disposition of our ordinary shares treated as ordinary income rather than capital gains and being subject to punitive interest charges on certain dividends and on the proceeds of the sale or other disposition of our ordinary shares. U.S. Holders would also be subject to annual information reporting requirements. In addition, if we were a PFIC in a taxable year in which we paid a dividend or the prior taxable year, such dividends would not be eligible to be taxed at the reduced rates applicable to qualified dividend income (as discussed above). Certain elections (including a mark-to-market election) may be available to U.S. Holders to mitigate some of the adverse tax consequences resulting from PFIC treatment. U.S. Holders should consult their own tax advisors regarding the application of the PFIC rules to their ownership of our ordinary shares.

**Information Reporting and Backup Withholding**

Information reporting to the IRS and backup withholding generally will apply to dividends in respect of our ordinary shares, and the proceeds from the sale or exchange of our ordinary shares, that are paid to U.S. Holders within the U.S. (and in certain cases, outside the United States), unless such U.S. Holder furnishes a correct taxpayer identification number and makes any other required certification (generally on IRS Form W-9) or otherwise establish an exemption from information reporting and backup withholding. Backup withholding is not an additional tax. Amounts withheld as backup withholding generally are allowed as a credit against a U.S. Holder’s U.S. federal income tax liability, and such holder may be entitled to obtain a refund of any excess amounts withheld under the backup withholding rules if such holder files an appropriate claim for refund with the IRS and furnishes any required information in a timely manner.

U.S. Holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules.

**Information with Respect to Foreign Financial Assets**

U.S. Holders who are individuals (and certain entities closely held by individuals) generally will be required to report our name, address and such information relating to an interest in our ordinary shares as is necessary to identify the class or issue of which our ordinary shares are a part. These requirements are subject to exceptions, including an exception for ordinary shares held in accounts maintained by certain financial institutions and an exception applicable if the aggregate value of all “specified foreign financial assets” (as defined in the Code) does not exceed (i) US $50,000 on the last day of the taxable year or (ii) US $75,000 at any time during the taxable year. U.S. Holders should consult their tax advisors regarding the application of these information reporting rules.

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|  | **F.** | **Dividends and Paying Agents** |

Not applicable.

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|  | **G.** | **Statement by Experts** |

Not applicable.

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|  | **H.** | **Documents on Display** |

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet site at www.sec.gov that contains reports, proxy and information statements and other information we have filed electronically with the SEC. As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We also make available on our website, free of charge, our annual report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.ysbiopharm.com. The information on, or that can be accessed through, our website is not part of this Annual Report.

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|  | **I.** | **Subsidiary Information** |

Not applicable.

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|  | **J.** | **Annual Report to Security Holders** |

Not applicable.

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

***Currency Risk***

A majority of our expenses are denominated in RMB and a significant portion of LakeShore Group and its subsidiaries’ assets and liabilities are denominated in RMB. RMB is not freely convertible into foreign currencies. In the PRC, certain foreign exchange transactions are required by law to be transacted only by authorized financial institutions at exchange rates set by the People’s Bank of China (the “PBOC”). Remittances in currencies other than RMB by us in China must be processed through the PBOC or other Company foreign exchange regulatory bodies which require certain supporting documentation in order to affect the remittance.

We maintain bank accounts in the PRC. On May 1, 2015, China’s new Deposit Insurance Regulation came into effect, pursuant to which banking financial institutions, such as commercial banks, established in the PRC are required to purchase deposit insurance for deposits in RMB and in foreign currency placed with them. Such Deposit Insurance Regulation would not be effective in providing complete protection for our accounts, as its aggregate deposits are higher than the compensation limit, which is RMB500,000 ($69,655) for one bank. However, we believe the risk of failure of any of these Chinese banks is remote. Bank failure is uncommon in the PRC and we believe that those Chinese banks that hold our cash are financially sound based on publicly available information.

***Concentration and political risks***

Currently, we have significant operations in the PRC. Accordingly, our business, financial condition and results of operations may be influenced by the political, economic and legal environment in the PRC, and by the general state of the PRC’s economy. Our operations in the PRC are subject to specific considerations and significant risks not typically associated with companies in North America and Western Europe. Our results may be adversely affected by changes in governmental policies in laws and regulations, anti-inflationary measures, currency conversion and remittance abroad, and rates and methods of taxation, among other things. Although we have not experienced losses from these situations and believe that it is in compliance with existing laws, this may not be indicative of future results

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***Interest rate risk***

Fluctuations in interest rates may negatively affect our financial condition and results of operations. We are exposed to floating interest rate risk on cash deposit and floating rate borrowings, and the risks due to changes in interest rates are not material. We have not used any derivative financial instruments to manage our interest risk exposure.

***Research and Development, Patents and Licenses***

For information about our proprietary intellectual properties and our research and development policies, see “Item 4. Information on the Company—B. Business Overview.”

***Trend Information***

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events since March 31, 2025 that are reasonably likely to have a material adverse effect on our revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future results of operations or financial condition.

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

Not applicable.

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**PART II**

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

None.

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

None.

**ITEM 15. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a 15(e) under the Exchange Act) as of the end of the period covered by this report, as required by Rule 13a 15(b) under the Exchange Act.

Based upon that evaluation, our management, with the participation of our chief executive officer and chief financial officer, has concluded that, as of March 31, 2025, our disclosure controls and procedures were ineffective because of the material weaknesses in our ICFR described below. However, we believe that the CFS included in this annual report on Form 20-F correctly present our financial position, results of operations and cash flows for the fiscal years covered thereby in all material respects.

**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) of the Exchange Act. Based on the assessment, our management has concluded that our internal control over financial reporting was not entirely effective as of March 31, 2025. As defined in the standards established by the PCAOB, a “material weakness” is a deficiency, or combination of deficiencies, in ICFR, such that there is a reasonable possibility that a material misstatement of our annual or interim CFS will not be prevented or detected on a timely basis.

2024 Material Weaknesses and Remedial Measures

We had previously identified certain material weaknesses in our internal control over financial reporting as of March 31, 2024, which were: 1) an ineffective internal control environment – certain “tone at the top” issues had resulted in extended delay in the implementation of critical entity level controls and process level controls across our operating entities; 2) insufficient accounting and finance personnel to effectively manage our pertinent operating, accounting and financial reporting risks, and design and implement policies and procedures to mitigate the related fraud risks; 3) a lack of qualified personnel in the accounting and financial reporting process who are knowledgeable of U.S. GAAP and pertinent SEC reporting requirements; and 4) a lack of policies and procedures to ensure timely account reconciliation and analysis, review and detection of errors or inaccuracies in the consolidated financial statements; and to enable adequate and sufficient disclosure in compliance with SEC reporting requirements.

During the fiscal year of 2025, under the oversight of the Board, our management implemented the following remedial actions to enhance the internal control framework, including:

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|  | 1) | We established a new management team. Under the leadership of our management team, an authorization management system has been established and implemented, while the online approval system is continuously improved. |

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|  | 2) | We recruited experienced financial management personnel to further improve the financial management team. We also reinforced the integrated management, including business planning, comprehensive budgeting, monthly business analysis and performance management. |

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|  | 3) | Our management provided ongoing training and oversight to ensure the execution of internal control. Additionally, regular cross-departmental meetings were organized to facilitate a better understanding of business processes and potential risks and to ensure the accuracy of financial reporting. |

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2025 Material Weaknesses and Remedial Measures

Despite the progress discussed above, two material weaknesses in our internal control over financial reporting are not yet fully addressed as of March 31, 2025, which were: 1) a lack of sufficient qualified personnel in the accounting and financial reporting process who are knowledgeable of U.S. GAAP and pertinent SEC reporting requirements; and 2) a lack of policies and procedures to ensure timely account reconciliation and analysis, review and detection of errors or inaccuracies in the consolidated financial statements; and to enable adequate and sufficient disclosure in compliance with SEC reporting requirements.

To continue to remediate these two identified material weaknesses, we are implementing a number of measures, including: (1) hiring additional accounting and financial personnels with appropriate knowledge and experience in U.S. GAAP accounting and SEC reporting, (2) organizing regular training on U.S. GAAP and SEC reporting requirements in regularly organized training for accounting department, (3) developing a U.S. GAAP accounting policies and procedures manual, which will be regularly maintained, reviewed and updated in accordance with the latest U.S. GAAP accounting standards, and (4) enhancing policies, procedures, and documentation of period-end closing activities to ensure completeness and accuracy in financial reporting.

However, we cannot assure you that we will remediate our material weaknesses in a timely manner. The process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligation. See “Risk Factors—Risks Related to Ownership of the Ordinary Shares—If we fail to remediate our material weaknesses and implement and maintain an effective system of internal control over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud.”

As a company with less than $1.235 billion in revenue for the last fiscal year, we qualify as an “emerging growth company” pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company’s ICFR.

**Attestation Report of the Registered Public Accounting Firm**

This Annual Report does not include an attestation report of our independent registered public accounting firm because we qualified as an “emerging growth company” as defined under the JOBS Act as of March 31, 2025.

**Changes in Internal Control over Financial Reporting**

Other than the remedial actions taken above for identified material weaknesses, there were no changes in our internal control over financial reporting that occurred during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materailly affect, our internal control over financial reporting.

**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our board of directors has determined that Mr. Adam Zhao, Mr. Thomas Xue and Mr. Chunyang Shao, independent directors (under the standards set forth in Rule 5605(a)(2) of the Nasdaq Stock Market Rules and Rule 10A 3 under the Exchange Act) and members of our audit committee, are our audit committee financial experts.

**ITEM 16B. CODE OF ETHICS**

Our board of directors has adopted our code of conduct and ethics, a code that applies to members of the board of directors including our chairman and other senior officers, including the chief executive officer, the chief financial officer and the chief medical officer. This code is publicly available on our website at www.lakeshorebio.com.

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**ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by Grant Thornton Zhitong Certified Public Accountants LLP for the fiscal year ended March 31, 2025. We did not pay any other fees to our auditors during the periods indicated below.

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|  |  | **Fiscal Year Ended  March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | | | | | |  |
|  |  | **RMB** | |  |  | **RMB** | |  |  | **US$** | |  |
| Audit fees(1) |  |  | - |  |  |  | 3,420,000 |  |  |  | 476,443 |  |
| Audit-related fees |  |  | - |  |  |  | - |  |  |  | - |  |
| Tax fees |  |  | - |  |  |  | - |  |  |  | - |  |
| All other fees |  |  | - |  |  |  | - |  |  |  | - |  |
| **Total** |  |  | - |  |  |  | **3,420,000** |  |  |  | **476,443** |  |

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|  | Note: |  |

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| --- | --- | --- |
|  | (1) | Audit fees are for the audit of our CFS and other audit or interim review services provided in connection with statutory and regulatory filings or engagements. The audit fees included fees for the audited financial statements included in our annual report on Form 20-F. |

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

Not applicable.

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

None.

**ITEM 16F. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT**

On November 12, 2024, the audit committee of the board of directors (the “Audit Committee”) approved the dismissal of Wei, Wei & Co., LLP (“WW&C”) as our independent registered public accounting firm, effective November 12, 2024, and the appointment of Grant Thornton Zhitong Certified Public Accountants LLP (“Grant Thornton”) as our new independent registered public accounting firm for the fiscal year ending March 31, 2025. Grant Thornton was formally engaged on November 12, 2024.

The reports of WW&C on our consolidated financial statements as of March 31, 2024 and 2023, and for each of the years in the three-year period ended March 31, 2024, contained no adverse opinion or disclaimer of opinion and were not qualified except for the inclusion of an emphasis of our going concern uncertainty.

During the fiscal years ended March 31, 2024 and 2023, and the subsequent period through November 12, 2024, there were (i) no “disagreements” (as that term is defined in Item 16F(a)(1)(iv) of Form 20-F) between us and WW&C on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of WW&C, would have caused WW&C to make reference to the subject matter of the disagreement in WW&C’s reports on our consolidated financial statements for such years, and (ii) no “reportable events” (as that term is defined in Item 16F(a)(1)(v) of Form 20-F).

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We provided WW&C with a copy of the disclosures we made in the current report on Form 6-K filed on November 12, 2024, and requested that WW&C furnish us with a letter addressed to the U.S. Securities and Exchange Commission (“SEC”) stating whether or not WW&C agrees with the disclosures made therein and, if not, stating the respects in which WW&C does not agree. A copy of WW&C’s letter to the SEC, dated November 12, 2024, is incorporated by reference herein as Exhibit 16.1 to this annual report.

During the fiscal years ended March 31, 2024 and 2023, and the subsequent period through November 12, 2024, neither the Company nor anyone on its behalf consulted with Grant Thornton regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, (ii) the type of audit opinion that might be rendered on the Company’s financial statements and neither a written report nor oral advice was provided to the Company that Grant Thornton concluded was an important factor considered by the Company in reaching a decision as to accounting, auditing or financial reporting issues, (iii) any matter that was the subject of a disagreement (as defined in Item 16F(a)(1)(iv) of Form 20-F and the related instructions), or (iv) any reportable event (as described in Item 16F(a)(1)(v) of Form 20-F).

**ITEM 16G. CORPORATE GOVERNANCE**

As a Cayman Islands company listed on Nasdaq, we are subject to the Nasdaq corporate governance listing standards. However, the Nasdaq Stock Market 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 listing standards. Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States.

We have elected to follow home country practice in lieu of the requirements that:

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|  | ● | the board of directors be comprised of a majority of independent directors under Nasdaq Rule 5605(b)(1); |

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|  | ● | independent directors must have regularly scheduled meetings at which only independent directors are present under Nasdaq Rule 5605(b)(2); |

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|  | ● | the compensation committee be comprised solely of independent directors under Nasdaq Rule 5605(d)(2)(A); |

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|  | ● | director nominees be selected or recommended for the board’s selection by a nominating committee comprised solely of independent directors under Nasdaq Rule 5605(e)(1); |

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|  | ● | an annual meeting of shareholders be held no later than one year after the end of a fiscal year under Nasdaq Rule 5620(a); |

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|  | ● | shareholder approval is required prior to the issuance of securities when the issuance or potential issuance will result in a change of control of the Company under Nasdaq Rule 5635(b); and |

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| --- | --- | --- |
|  | ● | Shareholder approval is required prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees, or consultants, subject to certain exemptions under Nasdaq Rule 5635(c). |

To the extent that we choose to follow home country practice with respect to corporate governance matters, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers. See “Item 3. Key Information—D. Risk Factors—Risks Related to Ownership of the Ordinary Shares—As an exempted company incorporated in the Cayman Islands, we have elected to follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq’s corporate governance requirements; these practices may afford less protection to shareholders.” Other than the home country practices described above, we are not aware of any significant differences between our corporate governance practices and those followed by U.S. domestic companies under Nasdaq Stock Market Rules.

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**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

**ITEM 16J. INSIDER TRADING POLICIES**

Not applicable.

**ITEM 16K. CYBERSECURITY**

***Risk Management and Strategy***

We have implemented and maintained various technical, physical, and organizational measures, processes, systems, standards and policies designed to identify, assess and manage material risks from cybersecurity threats to our computer-based communication systems and technology resources, peripheral equipment, and the information transmitted by, received from, or stored in these systems, whether distributed within the Company or externally (the “Information Systems”) , as well as any information that can be linked to an identified or identifiable person (the “Personal Data”). These measures, systems, policies include cybersecurity incident response policy, corporate information sharing and announcement policies, hardware purchase, use and storage policies, data storage and physical room management policies, corporate email and other data access account management system, office automation management system, system vulnerability management policy, disaster recovery or business continuity plans, security standards, encryption of data, network security controls, data segregation, access controls, physical security, asset management, tracking and disposal, systems monitoring and employee training.

We have established a specialized cybersecurity incident management team (the “CSI Management Team”) comprising representatives from both the center of internal control & compliance and IT department. Our CSI Management Team helps identify, assess and manage our cybersecurity threats and risks to the Information Systems and Personal Data by (i) investigating and gathering information regarding the scope of the suspected cybersecurity incidents, (ii) assuring that IS personnel determine appropriate actions to take to contain and remediate the cybersecurity incidents, (iii) taking appropriate action to preserve any relevant information and evidence, (iv) reviewing insurance availability and relevant obligations, (v) determining whether it is necessary or appropriate to make notifications to or engage the assistance of other parties, (vi) developing a response strategy and (vii) periodically reviewing and assessing the adequacy of this cybersecurity incident response policy, among others.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our CSI Management Team consults with the center of internal control & compliance and senior management to evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, qualified forensic investigators who are able to image affected devices, conduct a forensic computer investigation, or provide other services. We have strict procedures for the engagement of third-party service providers. Forensic investigators may only be engaged by our center of internal control & compliance or external legal counsel. To the extent additional third parties may need to be engaged to address a data security incident, those too shall be engaged by our center of internal control & compliance or external legal counsel. The center of internal control & compliance may establish and manage a list of pre-approved forensics providers and other third-party services providers.

For a description of the risks from cybersecurity threats that may materially affect our company and how they may do so, see “Item 3. Key information—D. Risk Factors—Risks Related to Extensive Government Regulations—We and our CROs are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.”

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***Governance***

Our board of directors addresses our company’s cybersecurity risk management as part of its general oversight function. Our head of IT department is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain of our management, including our chief executive officer, our chief financial officer, head of IT department and our senior network engineer. With the experience of setting up servers and firewalls, our senior network engineer is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, and overseeing the operation of our cybersecurity risks and cloud services. With the experience of software programming, the head of IT department is mainly responsible for supervising our IT and software departments, including helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. The head of IT department reports to our chief executive officer and our chief executive officer is responsible for approving budgets.

Our cybersecurity incident response and vulnerability management policies are designed to escalate certain cybersecurity incidents to cybersecurity incident management team (the “CSI management team”) depending on the circumstances, including our chief executive officers, chief financial officer and in-house general counsel. The CSI management team works with our company’s senior management team to help our company mitigate and remediate cybersecurity incidents of which they are notified. In addition, our company’s cybersecurity incident response and vulnerability management policies include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from our CSI management team concerning our company’s significant cybersecurity threats and risk and the processes our company has implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

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**PART III**

**ITEM 17. FINANCIAL STATEMENTS**

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

**ITEM 18. FINANCIAL STATEMENTS**

The consolidated financial statements of the Registrant are included at the end of this Annual Report.

**ITEM 19. EXHIBITS**

|  |  |  |
| --- | --- | --- |
| **Exhibit Number** |  | **Description** |
| 1.1 |  | [Second Amended and Restated Memorandum and Articles of Association of the Registrant as currently in effect (incorporated by reference to Exhibit 3.1 to the current report on Form 6-K (File No. 001-41598) furnished by the Registrant on September 27, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024082408/ea021589301ex3-1_lakeshore.htm) |
| 2.1 |  | [Description of Securities Registered under Section 12 of the U.S. Exchange Act (incorporated by reference to Exhibit 2.1 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex2-1_lakeshore.htm) |
| 2.2 |  | [Registrant’s Specimen Ordinary Share Certificate (incorporated by reference to Exhibit 2.2 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex2-2_lakeshore.htm) |
| 2.3 |  | [Registrant’s Specimen Warrant Certificate (incorporated by reference to Exhibit 2.3 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex2-3_lakeshore.htm) |
| 2.4(1) |  | [Warrant Agreement, dated as of June 8, 2021, between SPAC and Continental Stock Transfer & Trust Company](https://www.sec.gov/Archives/edgar/data/1839185/000119312521190073/d157526dex41.htm) |
| 2.5(2) |  | [Warrant Assignment Agreement, dated as of September 29, 2022, by and among the Registrant, SPAC and Continental Stock Transfer & Trust Company](https://www.sec.gov/Archives/edgar/data/1839185/000110465922104148/tm2226545d2_ex10-2.htm) |
| 4.1+ |  | [Form of Employment Agreement between the Registrant and its executive officers (incorporated by reference to Exhibit 4.1 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex4-1_lakeshore.htm) |
| 4.2(3) |  | [Form of Indemnification Agreement between the Registrant and its directors and executive officers](http://www.sec.gov/Archives/edgar/data/1946399/000110465922130315/tm2226545d15_ex10-6.htm) |
| 4.3\* |  | [Share and Warrant Purchase Agreement, dated as of July 8, 2025, between the Registrant and Crystal Peak Investment Inc.](ea024883901ex4-3_lakeshore.htm) |
| 4.4+ |  | [2020 Share Incentive Plan (incorporated by reference to Exhibit 4.4 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex4-4_lakeshore.htm) |
| 4.5+ |  | [Amended 2024 Share Incentive Plan (incorporated by reference to Exhibit 99.1 to the current report on Form 6-K (File No. 001-41598) furnished by the Registrant on March 12, 2025)](https://www.sec.gov/Archives/edgar/data/1946399/000121390025022976/ea023393401ex99-1_lakeshore.htm) |
| 4.6.1\* |  | [Financing Lease Agreement, dated as of April 1, 2025, between Liaoning Yisheng and Zhonghao Financial Leasing (Tianjin) Co., Ltd.](ea024883901ex4-6i_lakeshore.htm) |
| 4.6.2\* |  | [Financial Lease Agreement, dated as of April 1, 2025, between Liaoning Yisheng and Zhonghao Financial Leasing (Tianjin) Co., Ltd.](ea024883901ex4-6ii_lakeshore.htm) |
| 8.1\* |  | [List of Principal Subsidiaries](ea024883901ex8-1_lakeshore.htm) |
| 11.1 |  | [Code of Business Conduct and Ethics of the Registrant (incorporated by reference to Exhibit 11.1 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex11-1_lakeshore.htm) |
| 11.2 |  | [Insider Trading Policy (incorporated by reference to Exhibit 11.2 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex11-2_lakeshore.htm) |
| 12.1\* |  | [Principal Executive Officer Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](ea024883901ex12-1_lakeshore.htm) |
| 12.2\* |  | [Principal Financial Officer Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](ea024883901ex12-2_lakeshore.htm) |
| 13.1\*\* |  | [Principal Executive Officer Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](ea024883901ex13-1_lakeshore.htm) |
| 13.2\*\* |  | [Principal Financial Officer Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](ea024883901ex13-2_lakeshore.htm) |
| 15.1\* |  | [Consent of Wei, Wei & Co., LLP. — Independent Registered Public Accounting Firm](ea024883901ex15-1_lakeshore.htm) |
| 15.2\* |  | [Consent of Grant Thornton Zhitong Certified Public Accountants LLP](ea024883901ex15-2_lakeshore.htm) |
| 15.3\* |  | [Consent of Jingtian & Gongcheng](ea024883901ex15-3_lakeshore.htm) |

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| 15.4\* |  | [Consent of Maples and Calder (Hong Kong) LLP](ea024883901ex15-4_lakeshore.htm) |
| 16.1 |  | [Letter from Predecessor Auditor (incorporated by reference to Exhibit 99.1 to the current report on Form 6-K (File No. 001-41598) filed by the Registrant on November 12, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024096230/ea022064801ex99-1_lakeshore.htm) |
| 97.1 |  | [Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97.1 to the annual report on Form 20-F (File No. 001-41598) filed by the Registrant on August 15, 2024)](https://www.sec.gov/Archives/edgar/data/1946399/000121390024069344/ea021059501ex97-1_lakeshore.htm) |
| 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 |  | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

|  |  |  |
| --- | --- | --- |
|  | \* | Filed with this Annual Report. |

|  |  |  |
| --- | --- | --- |
|  | \*\* | Furnished with this Annual Report. |

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| --- | --- | --- |
|  | + | Indicates management contract or compensatory plan or arrangement. |

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| --- | --- | --- |
|  | (1) | Previously filed on the SPAC’s Current Report on Form 8-K (File No. 001-40466), dated June 14, 2021 and incorporated herein by reference. |

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|  | (2) | Previously filed on the SPAC’s Current Report on Form 8-K (File No. 001-40466), dated September 29, 2022 and incorporated herein by reference. |

|  |  |  |
| --- | --- | --- |
|  | (3) | Previously filed on the Registrant’s Registration Statement on Form F-4 (File No. 333-269031), dated December 28, 2022 and incorporated herein by reference. |

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**SIGNATURES**

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

|  |  |  |
| --- | --- | --- |
|  | **LakeShore Biopharma Co., Ltd** | |
|  |  |  |
|  | By: | /s/ Xu Wang |
|  | Name: | Xu Wang |
| Date: July 31, 2025 | Title: | Director and Chief Executive Officer |

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**LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

LakeShore Biopharma Co., Ltd

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of LakeShore Biopharma Co., Ltd (formerly YS Biopharma Co., Ltd.) and subsidiaries (the “Company”) as of March 31, 2025, the related consolidated statements of operations and comprehensive loss, changes in shareholders’ (deficit)/equity, and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2025, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

**Going Concern Uncertainty**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2 to the financial statements, the Company incurred a net loss of RMB99.98 million (US$13.93 million) during the year ended March 31, 2025, and as of that date, the Company had an accumulated deficit of approximately RMB2.41 billion (US$335.39 million) and negative operating cash flow. These conditions, along with other matters including ongoing litigation as set forth in Note 2, raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Ongoing Litigation**

As described in Note 18, the Company has been involved in certain legal proceedings in the Cayman Islands and arbitration claims in China against Mr. Yi Zhang, the former chairperson of the Board. An unfavorable outcome in either or both lawsuits may have material adverse effects on the Company’s continuing operations, cash flows and liquidity, and financial position.

**Convenience Translation**

Our audit also comprehended the translation of Renminbi amounts into United States dollar amounts and, in our opinion, such translation has been made in conformity with the basis stated in Note 3 to the financial statements. Such United States dollar amounts are presented solely for the convenience of readers outside the People’s Republic of China.

**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 audit 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, where 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Grant Thornton Zhitong Certified Public Accountants LLP

We have served as the Company’s auditor since 2024.

Shanghai, China

July 31, 2025

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

A logo for a company

AI-generated content may be incorrect.

|  |  |  |
| --- | --- | --- |
| A close-up of a phone number  AI-generated content may be incorrect. |  | To the Board of Directors and Shareholders of  LakeShore Biopharma Co., Ltd    **Opinion on the Financial Statements**    We have audited the accompanying consolidated balance sheet of LakeShore Biopharma Co., Ltd (formerly YS Biopharma Co., Ltd) and Subsidiaries (the “Company”) as of March 31, 2024, and the related consolidated statements of operations and comprehensive loss, changes in shareholders’ (deficit)/equity, and cash flows for each of the years in the two-year period ended March 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2024, in conformity with accounting principles generally accepted in the United States of America.    **Going Concern Uncertainty**    The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2 to the financial statements, the Company has suffered recurring losses from operations, negative cash flows from operations and had an accumulated deficit of approximately RMB 2.3 billion as of March 31, 2024. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.    **Convenience Translation**    Our audits also comprehended the translation of Renminbi amounts into United States dollar amounts and, in our opinion, such translation has been made in conformity with the basis stated in Note 3 to the financial statements. Such United States dollar amounts are presented solely for the convenience of readers outside the People’s Republic of China.  **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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.    /s/ Wei, Wei & Co., LLP    We served as the Company’s auditor from 2022 to 2024.  Flushing, New York  August 15, 2024 |

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**LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **ASSETS** |  |  | |  |  |  | |  |  |  | |  |
| **Current assets** |  |  | |  |  |  | |  |  |  | |  |
| Cash |  |  | 246,351,231 |  |  |  | 28,083,556 |  |  | $ | 3,912,340 |  |
| Restricted cash |  |  | 200,000 |  |  |  | 79,401,410 |  |  |  | 11,061,465 |  |
| Accounts receivable |  |  | 444,161,291 |  |  |  | 500,916,815 |  |  |  | 69,783,067 |  |
| Advance to suppliers |  |  | 1,662,739 |  |  |  | 1,687,964 |  |  |  | 235,151 |  |
| Inventories |  |  | 203,422,602 |  |  |  | 227,591,892 |  |  |  | 31,705,984 |  |
| Prepaid expenses and other current assets |  |  | 7,370,089 |  |  |  | 4,536,363 |  |  |  | 631,964 |  |
| **Total current assets** |  |  | **903,167,952** |  |  |  | **842,218,000** |  |  |  | **117,329,971** |  |
| **Non-current assets** |  |  |  |  |  |  |  |  |  |  |  |  |
| Property, plant and equipment |  |  | 473,348,006 |  |  |  | 413,501,445 |  |  |  | 57,605,172 |  |
| Operating lease right-of-use assets |  |  | 7,275,367 |  |  |  | 847,331 |  |  |  | 118,042 |  |
| Deferred tax assets |  |  | 23,634,189 |  |  |  | 27,946,500 |  |  |  | 3,893,247 |  |
| Intangible assets |  |  | 71,245,336 |  |  |  | 72,854,656 |  |  |  | 10,149,432 |  |
| Other non-current assets |  |  | 34,356,506 |  |  |  | 10,295,279 |  |  |  | 1,434,242 |  |
| **Total non-current assets** |  |  | **609,859,404** |  |  |  | **525,445,211** |  |  |  | **73,200,135** |  |
| **Total assets** |  |  | **1,513,027,356** |  |  |  | **1,367,663,211** |  |  | **$** | **190,530,106** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **LIABILITIES AND SHAREHOLDERS’ EQUITY** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Current liabilities** |  |  |  |  |  |  |  |  |  |  |  |  |
| Bank loans and other borrowings |  |  | 318,540,732 |  |  |  | 390,440,095 |  |  | $ | 54,392,479 |  |
| Accounts payable |  |  | 67,774,798 |  |  |  | 49,551,779 |  |  |  | 6,903,093 |  |
| Accrued expenses and other liabilities |  |  | 408,737,969 |  |  |  | 382,847,958 |  |  |  | 53,334,812 |  |
| Operating lease liabilities |  |  | 5,156,540 |  |  |  | 457,012 |  |  |  | 63,667 |  |
| Deferred government grants |  |  | 2,015,693 |  |  |  | 1,455,678 |  |  |  | 202,792 |  |
| **Total current liabilities** |  |  | **802,225,732** |  |  |  | **824,752,522** |  |  |  | **114,896,843** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Non-current liabilities** |  |  |  |  |  |  |  |  |  |  |  |  |
| Bank loans and other borrowings |  |  | 98,983,780 |  |  |  | 23,503,471 |  |  |  | 3,274,285 |  |
| Operating lease liabilities |  |  | 1,783,593 |  |  |  | - |  |  |  | - |  |
| Deferred government grants |  |  | 20,279,945 |  |  |  | 16,207,745 |  |  |  | 2,257,912 |  |
| Warrants liability |  |  | 4,548,004 |  |  |  | 3,444,842 |  |  |  | 479,903 |  |
| **Total non-current liabilities** |  |  | **125,595,322** |  |  |  | **43,156,058** |  |  |  | **6,012,100** |  |
| **Total liabilities** |  |  | **927,821,054** |  |  |  | **867,908,580** |  |  |  | **120,908,943** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Shareholders’equity** |  |  |  |  |  |  |  |  |  |  |  |  |
| Ordinary shares, par value US$0.0002 per share; 250,000,000 shares authorized; 19,022,795 and 20,766,531 shares issued and outstanding as of March 31, 2024 and 2025, respectively \* |  |  | 26,105 |  |  |  | 28,603 |  |  |  | 3,985 |  |
| Additional paid-in capital |  |  | 2,950,862,914 |  |  |  | 2,964,482,986 |  |  |  | 412,984,172 |  |
| Accumulated deficit |  |  | (2,307,502,836 | ) |  |  | (2,407,485,287 | ) |  |  | (335,388,438 | ) |
| Accumulated other comprehensive loss |  |  | (58,179,881 | ) |  |  | (57,271,671 | ) |  |  | (7,978,556 | ) |
| **Total shareholders’ equity** |  |  | **585,206,302** |  |  |  | **499,754,631** |  |  |  | **69,621,163** |  |
| **Total liabilities and shareholders’ equity** |  |  | **1,513,027,356** |  |  |  | **1,367,663,211** |  |  | **$** | **190,530,106** |  |

|  |  |  |
| --- | --- | --- |
|  | \* | Gives retroactive effect to the Share Consolidation in October 2024. |

The accompanying notes are an integral part of these consolidated financial statements.

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**LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Revenues** |  |  | **687,201,070** |  |  |  | **573,418,256** |  |  |  | **614,961,584** |  |  | **$** | **85,670,723** |  |
| Cost of revenues |  |  | 153,360,262 |  |  |  | 117,688,301 |  |  |  | 107,772,147 |  |  |  | 15,013,812 |  |
| **Gross profit** |  |  | **533,840,808** |  |  |  | **455,729,955** |  |  |  | **507,189,437** |  |  |  | **70,656,911** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Operating expenses:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Selling and marketing |  |  | 272,927,356 |  |  |  | 301,259,528 |  |  |  | 281,429,426 |  |  |  | 39,206,128 |  |
| General and administrative |  |  | 72,939,790 |  |  |  | 140,086,062 |  |  |  | 128,967,761 |  |  |  | 17,966,588 |  |
| Impairment loss on inventory, property, plant and equipment and other assets |  |  | 8,655,487 |  |  |  | 157,415,875 |  |  |  | 36,715,041 |  |  |  | 5,114,798 |  |
| Research and development |  |  | 318,700,526 |  |  |  | 302,800,992 |  |  |  | 146,369,093 |  |  |  | 20,390,779 |  |
| **Total operating expenses** |  |  | **673,223,159** |  |  |  | **901,562,457** |  |  |  | **593,481,321** |  |  |  | **82,678,293** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Loss from operations** |  |  | **(139,382,351** | **)** |  |  | **(445,832,502** | **)** |  |  | **(86,291,884** | **)** |  |  | **(12,021,382** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Other income (expenses):** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Late fees for taxes other than income tax |  |  | (3,603 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Late fees for social security insurance |  |  | (747,609 | ) |  |  | (756,201 | ) |  |  | (454,863 | ) |  |  | (63,367 | ) |
| Government grants |  |  | 26,072,517 |  |  |  | 20,708,778 |  |  |  | 5,125,566 |  |  |  | 714,046 |  |
| Financial expenses |  |  | (30,857,673 | ) |  |  | (44,344,808 | ) |  |  | (15,739,410 | ) |  |  | (2,192,668 | ) |
| Fair value changes of warrant liability |  |  | 21,358 |  |  |  | 4,458,844 |  |  |  | 1,149,792 |  |  |  | 160,178 |  |
| Other income(expense) |  |  | 551,760 |  |  |  | 10,572,411 |  |  |  | (4,718,525 | ) |  |  | (657,341 | ) |
| **Total other income (expense)** |  |  | **(4,963,250** | **)** |  |  | **(9,360,976** | **)** |  |  | **(14,637,440** | **)** |  |  | **(2,039,152** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Loss before income taxes** |  |  | **(144,345,601** | **)** |  |  | **(455,193,478** | **)** |  |  | **(100,929,324** | **)** |  |  | **(14,060,534** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Income tax benefit(expense)** |  |  | **(1,133,504** | **)** |  |  | **21,728,607** |  |  |  | **946,873** |  |  |  | **131,910** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Net loss** |  |  | **(145,479,105** | **)** |  |  | **(433,464,871** | **)** |  |  | **(99,982,451** | **)** |  |  | **(13,928,624** | **)** |
| Accretion to redemption value of convertible redeemable preferred shares |  |  | (137,991,697 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| **Net loss attributable to LakeShore Group** |  |  | **(283,470,802** | **)** |  |  | **(433,464,871** | **)** |  |  | **(99,982,451** | **)** |  | **$** | **(13,928,624** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Net loss** |  |  | **(145,479,105** | **)** |  |  | **(433,464,871** | **)** |  |  | **(99,982,451** | **)** |  | **$** | **(13,928,624** | **)** |
| Other comprehensive income (loss), net of tax: Foreign currency translation adjustment |  |  | (137,500,063 | ) |  |  | (3,767,798 | ) |  |  | 908,210 |  |  |  | 126,523 |  |
| **Total comprehensive loss** |  |  | **(282,979,168** | **)** |  |  | **(437,232,669** | **)** |  |  | **(99,074,241** | **)** |  | **$** | **(13,802,101** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Loss per share\*:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| – Basic and Diluted |  |  | (23.55 | ) |  |  | (40.54 | ) |  |  | (5.22 | ) |  | $ | (0.73 | ) |
| **Weighted average number of ordinary shares outstanding\*:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| – Basic and Diluted |  |  | 6,178,547 |  |  |  | 10,692,312 |  |  |  | 19,158,907 |  |  |  | 19,158,907 |  |

|  |  |  |
| --- | --- | --- |
|  | \* | Gives retroactive effect to the Share Consolidation in October 2024. |

The accompanying notes are an integral part of these consolidated financial statements.

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**LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS’ (DEFICIT)/EQUITY**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | **Ordinary shares\*** | | | | | |  |  | **Additional  paid-in** | |  |  |  | |  |  | **Accumulated  other  comprehensive** | |  |  | **Total  stockholders’** | |  |
|  |  | **Shares** | |  |  | **Amount** | |  |  | **capital** | |  |  | **Deficit** | |  |  | **income/(loss)** | |  |  | **(deficit)/equity** | |  |
|  |  |  | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |
| **Balance as of March 31, 2022** |  |  | **6,182,788** |  |  |  | **7,978** |  |  |  | **808,502,018** |  |  |  | **(1,590,567,163** | **)** |  |  | **83,087,979** |  |  |  | **(698,969,188** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accretion to redemption value of convertible redeemable preferred shares |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (137,991,697 | ) |  |  | - |  |  |  | **(137,991,697** | **)** |
| Net loss |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (145,479,105 | ) |  |  | - |  |  |  | **(145,479,105** | **)** |
| Conversion of mezzanine equity |  |  | 2,174,086 |  |  |  | 3,007 |  |  |  | 1,636,894,077 |  |  |  |  |  |  |  | - |  |  |  | **1,636,897,084** |  |
| Share-based compensation |  |  | (14,375 | ) |  |  | (20 | ) |  |  | 3,505,021 |  |  |  | - |  |  |  | - |  |  |  | **3,505,001** |  |
| Issuance of common stock |  |  | 963,320 |  |  |  | 1,332 |  |  |  | 216,376,861 |  |  |  | - |  |  |  | - |  |  |  | **216,378,193** |  |
| Warrant from business combination |  |  | - |  |  |  | - |  |  |  | (8,870,007 | ) |  |  | - |  |  |  | - |  |  |  | **(8,870,007** | **)** |
| Additional paid-in capital from business combination |  |  | - |  |  |  | - |  |  |  | 483,066 |  |  |  | - |  |  |  | - |  |  |  | **483,066** |  |
| Foreign currency translation adjustment |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (137,500,062 | ) |  |  | **(137,500,062** | **)** |
| **Balance as of March 31, 2023** |  |  | **9,305,819** |  |  |  | **12,297** |  |  |  | **2,656,891,036** |  |  |  | **(1,874,037,965** | **)** |  |  | **(54,412,083** | **)** |  |  | **728,453,285** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Net loss |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (433,464,871 | ) |  |  | - |  |  |  | **(433,464,871** | **)** |
| Share-based compensation |  |  | 190,000 |  |  |  | 270 |  |  |  | 9,789,416 |  |  |  | - |  |  |  | - |  |  |  | **9,789,686** |  |
| Issuance of common stock |  |  | 9,526,976 |  |  |  | 13,538 |  |  |  | 284,182,462 |  |  |  | - |  |  |  | - |  |  |  | **284,196,000** |  |
| Foreign currency translation adjustment |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (3,767,798 | ) |  |  | **(3,767,798** | **)** |
| **Balance as of March 31, 2024** |  |  | **19,022,795** |  |  |  | **26,105** |  |  |  | **2,950,862,914** |  |  |  | **(2,307,502,836** | **)** |  |  | **(58,179,881** | **)** |  |  | **585,206,302** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Issuance of common stock |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Net loss |  |  | - |  |  |  | - |  |  |  | - |  |  |  | (99,982,451 | ) |  |  | - |  |  |  | **(99,982,451** | **)** |
| Share-based compensation |  |  | 1,743,736 |  |  |  | 2,498 |  |  |  | 13,620,072 |  |  |  |  |  |  |  |  |  |  |  | **13,622,570** |  |
| Foreign currency translation adjustment |  |  | - |  |  |  | - |  |  |  | - |  |  |  | - |  |  |  | 908,210 |  |  |  | **908,210** |  |
| **Balance as of March 31, 2025(in RMB)** |  |  | **20,766,531** |  |  |  | **28,603** |  |  |  | **2,964,482,986** |  |  |  | **(2,407,485,287** | **)** |  |  | **(57,271,671** | **)** |  |  | **499,754,631** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Balance as of March 31, 2025(in US$)** |  |  | **20,766,531** |  |  |  | **3,985** |  |  |  | **412,984,172** |  |  |  | **(335,388,438** | **)** |  |  | **(7,978,556** | **)** |  |  | **69,621,163** |  |

|  |  |
| --- | --- |
| \* | Gives retroactive effect to the Share Consolidation in October 2024. |

The accompanying notes are an integral part of these consolidated financial statements.

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**LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Cash flows from operating activities:** |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Net loss |  |  | (145,479,105 | ) |  |  | (433,464,871 | ) |  |  | (99,982,451 | ) |  | $ | (13,928,624 | ) |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Deferred income taxes expense (benefit) |  |  | 1,133,504 |  |  |  | (21,728,608 | ) |  |  | (4,312,310 | ) |  |  | (600,751 | ) |
| Depreciation of property, plant and equipment |  |  | 29,735,024 |  |  |  | 35,373,927 |  |  |  | 29,733,103 |  |  |  | 4,142,139 |  |
| Amortization of intangible assets |  |  | 6,952,783 |  |  |  | 6,811,456 |  |  |  | 6,918,505 |  |  |  | 963,822 |  |
| Loss on disposal of property, plant and equipment |  |  | - |  |  |  | 13,135 |  |  |  | 9,777,030 |  |  |  | 1,362,045 |  |
| Provision for impairment of property, plant and equipment |  |  | - |  |  |  | 80,236,996 |  |  |  | 17,801,862 |  |  |  | 2,479,990 |  |
| Provision for impairment of intangible assets |  |  | - |  |  |  | - |  |  |  | 10,384,000 |  |  |  | 1,446,602 |  |
| Provision for impairment of other non- current assets |  |  | - |  |  |  | - |  |  |  | 5,638,970 |  |  |  | 785,569 |  |
| Share-based compensation |  |  | 3,505,001 |  |  |  | 9,789,686 |  |  |  | 13,557,214 |  |  |  | 1,888,665 |  |
| Bad debt provision of accounts receivable |  |  | 10,750,949 |  |  |  | 4,987,206 |  |  |  | 2,890,210 |  |  |  | 402,637 |  |
| Write-down (reversal) of inventories to net realizable value |  |  | (723,583 | ) |  |  | 68,221,017 |  |  |  | - |  |  |  | - |  |
| Non-cash lease expense |  |  | 4,423,612 |  |  |  | 4,778,623 |  |  |  | 3,142,729 |  |  |  | 437,816 |  |
| Fair value changes of warrant liability |  |  | (21,358 | ) |  |  | (4,458,844 | ) |  |  | (1,149,792 | ) |  |  | (160,178 | ) |
| Changes in operating assets and liabilities: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inventories |  |  | (18,151,804 | ) |  |  | (86,262,667 | ) |  |  | (24,169,290 | ) |  |  | (3,367,040 | ) |
| Accounts receivable |  |  | (165,247,635 | ) |  |  | 13,903,295 |  |  |  | (59,645,734 | ) |  |  | (8,309,288 | ) |
| Prepaid expenses and other current assets |  |  | 8,992,573 |  |  |  | (5,289,535 | ) |  |  | 7,468,933 |  |  |  | 1,040,502 |  |
| Accounts payable |  |  | 49,628,389 |  |  |  | (12,664,691 | ) |  |  | (18,223,019 | ) |  |  | (2,538,661 | ) |
| Accrued expenses and other liabilities |  |  | 43,029,496 |  |  |  | 53,220,366 |  |  |  | (10,902,919 | ) |  |  | (1,518,896 | ) |
| Deferred government grants |  |  | (6,447,010 | ) |  |  | (3,606,570 | ) |  |  | (4,632,215 | ) |  |  | (645,317 | ) |
| Operating lease liabilities |  |  | (4,550,232 | ) |  |  | (5,089,524 | ) |  |  | (5,276,553 | ) |  |  | (735,080 | ) |
| **Net cash used in operating activities** |  |  | (182,469,396 | ) |  |  | **(295,229,603** | **)** |  |  | **(120,981,727** | **)** |  |  | **(16,854,048** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Cash flows from investing activities:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Proceeds from disposal of property, plant and equipment |  |  | 68,001 |  |  |  | - |  |  |  | 852,114 |  |  |  | 118,709 |  |
| Purchases of property, plant and equipment |  |  | (52,758,124 | ) |  |  | (44,250,714 | ) |  |  | (12,708,614 | ) |  |  | (1,770,446 | ) |
| Purchases of intangible assets |  |  | (4,291,597 | ) |  |  | - |  |  |  | (5,150,000 | ) |  |  | (717,450 | ) |
| **Net cash used in investing activities** |  |  | **(56,981,720** | **)** |  |  | **(44,250,714** | **)** |  |  | **(17,006,500** | **)** |  |  | **(2,369,187** | **)** |
| **Cash flows from financing activities:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Proceeds from issuance of ordinary shares |  |  | - |  |  |  | 284,196,000 |  |  |  | - |  |  |  | - |  |
| Proceeds from business combination |  |  | 252,457,329 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Offering cost |  |  | (35,884,661 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| Proceeds from bank loans and other borrowings |  |  | 247,387,392 |  |  |  | 337,851,075 |  |  |  | 334,817,619 |  |  |  | 46,643,674 |  |
| Repayment of bank loans and other borrowings |  |  | (146,510,134 | ) |  |  | (416,785,723 | ) |  |  | (338,398,565 | ) |  |  | (47,142,538 | ) |
| **Net cash provided by (used in) financing activities** |  |  | **317,449,926** |  |  |  | **205,261,352** |  |  |  | **(3,580,946** | **)** |  |  | **(498,864** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Effect of foreign exchange rate on cash |  |  | 21,303,512 |  |  |  | 10,400,371 |  |  |  | 2,502,908 |  |  |  | 348,682 |  |
| **Net (decrease) increase in cash** |  |  | 99,302,322 |  |  |  | (123,818,594 | ) |  |  | (139,066,265 | ) |  |  | (19,373,417 | ) |
| **Cash and restricted cash at the beginning of the year** |  |  | 271,067,503 |  |  |  | 370,369,825 |  |  |  | 246,551,231 |  |  |  | 34,347,222 |  |
| **Cash and restricted cash at the end of the year** |  |  | 370,369,825 |  |  |  | 246,551,231 |  |  |  | 107,484,966 |  |  | $ | 14,973,805 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Supplemental disclosures of cash flow information:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Income taxes paid |  |  | - |  |  |  | - |  |  |  | 3,365,438 |  |  |  | 468,841 |  |
| Interest paid |  |  | 27,289,057 |  |  |  | 30,131,238 |  |  |  | 23,222,931 |  |  | $ | 3,235,203 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Non-cash transactions:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accretion to redemption value of convertible redeemable preferred shares |  |  | 137,991,697 |  |  |  | - |  |  |  | - |  |  | $ | - |  |
| Operating right-of-use assets recognized for related operating lease liabilities |  |  | 331,218 |  |  |  | 829,703 |  |  |  | - |  |  | $ | - |  |
| Equity transaction from warrants |  |  | (8,870,007 | ) |  |  | - |  |  |  | - |  |  | $ | - |  |
| Equity transaction from preferred shares |  |  | 1,636,897,084 |  |  |  | - |  |  |  | - |  |  | $ | - |  |

The accompanying notes are an integral part of these consolidated financial statements.

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**LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2025 and 2024**

**NOTE 1 –** **ORGANIZATION AND BUSINESS DESCRIPTION**

LakeShore Biopharma Co., Ltd (“LakeShore Biopharma”), formerly known as YS Biopharma Co., Ltd. (with the name effective on May 23, 2024), was incorporated under the laws of the Cayman Islands as an exempted company with limited liability in November 2020. It owns six companies and their subsidiaries that were incorporated in the Cayman Islands, Singapore, Hong Kong, Philippines and the People’s Republic of China (“China” or the “PRC”) (collectively, the “Company” or “LakeShore Group”). LakeShore Group is principally engaged in the research, development, manufacturing and sale of vaccines and therapeutic biologics. It developed a PIKA immunomodulating technology platform and a series of product candidates targeting rabies, hepatitis B, influenza and other indications. It also produces and sells YSJA™ (依生君安™) rabies vaccine, the first aluminum-free lyophilized rabies vaccine launched in China.

***Business Combination***

On August 15, 2022, Oceanview Bioscience Acquisition Co., Ltd. (“Oceanview Bioscience”) and Hudson Biomedical Group Co., Ltd. (“Hudson Biomedical”) were incorporated under the laws of Cayman Islands as exempted companies with limited liability. The companies were incorporated to effect a merger with Summit Healthcare Acquisition Corp (“Summit”), a Special Purpose Acquisition Company (“SPAC”).

On September 29, 2022, LakeShore Biopharma entered into the Business Combination Agreement with Summit Oceanview Bioscience Acquisition Co., Ltd., (“Merger Sub I”) and Hudson Biomedical Group Co., Ltd., (“Merger Sub II”). The Business Combination Agreement provides for (1) the merger of Merger Sub I with and into Summit (the “First Merger”), with Summit surviving the First Merger as the surviving entity (the “Surviving Entity”) and becoming a wholly-owned subsidiary of LakeShore Biopharma, and (2) the merger of the Surviving Entity with and into Merger Sub II (the “Second Merger,” and together with the First Merger, the “Mergers,” together with other transactions contemplated by the Business Combination Agreement, the “Business Combination”), with Merger Sub II surviving the Second Merger as the surviving company (the “Surviving Company”) and remaining as a wholly-owned subsidiary of LakeShore Biopharma.

In accordance with the Business Combination Agreement, on the date of closing of the Mergers (“First Merger and Second Merger”), (1) each LakeShore Biopharma’s preferred share was converted into one pre-consolidation Ordinary Share; (2) every four of the pre-consolidation Ordinary Shares and every four pre-consolidation options of LakeShore Biopharma were consolidated into one Ordinary Share and one option of LakeShore Biopharma, respectively, subject to rounding up to the nearest whole number of Ordinary Shares.

On March 16, 2023 (the “Closing Date”), LakeShore Biopharma announced the completion of its business combination with Summit pursuant to the above Business Combination Agreement.

On May 9, 2023, LakeShore Biopharma (Philippines) Inc. (“Philippines LakeShore”) was incorporated under the laws of Philippines as an entity owned by LakeShore Group. Philippines LakeShore was incorporated for the purpose of research, development, producing, wholesaling and commercializing pharmaceutical products, including vaccines and other biological products.

On April 5, 2024, LakeShore Tech Hong Kong Limited and LakeShore Bio Hong Kong Limited were incorporated as holding company under the laws of Hong Kong as entities owned by LakeShore Biopharma.

On April 19, 2024, Hu’an Yuanhang Technology (Beijing) Co., Ltd was incorporated for research and development, with name changed to Hu’an Yuanhang Biotechnology (Beijing) Co., Ltd on July 11, 2024. On June 3, 2025, the name is changed from Hu’an Yuanhang Biotechnology (Beijing) Co., Ltd to Hu’an Biotechnology (Beijing) Co., Ltd.

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Below is LakeShore Group’s current legal entity structure:

A diagram of a diagram

AI-generated content may be incorrect.

As of March 31, 2025, LakeShore Group consists of the following legal entities:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Legal Entity** |  | **Nature of Operations** |  | **Date of Incorporation** |  | **Place of  Incorporation** |
| LakeShore Biopharma Co., Ltd. (“LakeShore Biopharma”)\*\*\* |  | Holding Company |  | November 16, 2020 |  | Cayman Islands |
| YishengBio (Hong Kong) Holdings Limited (“HK Yisheng”) |  | Holding Company |  | December 28, 2020 |  | Hong Kong |
| LakeShore Biopharma (Singapore) Pte. Ltd. (“Singapore LakeShore”)\*\* |  | Research and development of vaccines and therapeutic biologics |  | November 28, 2009 |  | Singapore |
| Liaoning Yisheng Biopharma Co., Ltd. (“Liaoning Yisheng”)\* |  | Research and development, manufacturing and commercialization of vaccines and therapeutic biologics |  | May 26, 1994 |  | PRC |
| Beijing Yisheng Biotechnology Co., Ltd. (“Beijing Yisheng”) |  | Research and development of vaccines and therapeutic biologics |  | February 4, 2021 |  | PRC |
| Hudson Biomedical Group Co., Ltd. |  | Purpose of effecting a merger |  | August 15, 2022 |  | Cayman Islands |
| LakeShore Biopharma (Philippines) Inc. (“Philippines LakeShore”) |  | Researching, developing, producing, wholesaling and commercializing pharmaceutical products |  | May 9, 2023 |  | Philippines |
| LakeShore Tech Hong Kong Limited |  | Holding Company |  | April 5, 2024 |  | Hong Kong |
| LakeShore Bio Hong Kong Limited |  | Holding Company |  | April 5, 2024 |  | Hong Kong |
| Hu’an Yuanhang Biotechnology (Beijing) Co., Ltd |  | Research and development of vaccines and therapeutic biologics |  | April 19, 2024 |  | PRC |

|  |  |  |
| --- | --- | --- |
|  | \* | Liaoning Yisheng was incorporated May 26, 1994, and acquired by LakeShore Group in fiscal 2005.    On March 26, 2024, Liaoning Yisheng Biopharma Co., Ltd. Beijing Branch (“Liaoning Yisheng Beijing Branch”) was incorporated for research and development, manufacturing and commercialization of vaccines and therapeutic biologics. |

|  |  |  |
| --- | --- | --- |
|  | \*\* | Singapore LakeShore was incorporated November 28, 2009, and acquired by LakeShore Group in fiscal 2011.    Singapore LakeShore was formerly known as Yisheng Biopharma (Singapore) Pte. Ltd. with the name effective on July 22, 2024. |

|  |  |  |
| --- | --- | --- |
|  | \*\*\* | LakeShore Biopharma, formerly known as YS Biopharma Co., Ltd, with the name effective on May 23, 2024. |

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**NOTE 2 –GOING CONCERN UNCERTAINTY**

As reflected in the accompanying consolidated financial statements (“CFS”), the Company reported net loss of RMB145,479,105, RMB433,464,871 and RMB99,982,451 for the years ended March 31, 2023, 2024 and 2025, respectively. In addition, the Company had negative cash flows from operations in each of the years during the three-year period ended March 31, 2025, and reported accumulated deficit of RMB2,307,502,836 and RMB2,407,485,287 as of March 31, 2024 and 2025.

In assessing its liquidity, management monitors and analyzes the Company’s cash flow requirements, its ability to generate sufficient revenue sources in the future, and its operating and capital expenditure commitments. As of March 31, 2025, the Company had cash of approximately RMB107.5 million (US$15.0 million). As of March 31, 2025, the Company had outstanding bank loans and other borrowings of approximately RMB413.9 million (US$57.7 million) from various financial institutions.

The Company’s ability to continue as a going concern is dependent on management’s ability to successfully execute its business plan, which includes increasing revenues while controlling operating expenses, and continuing to gain support from outside sources of financing. The Company believes that available loan facility and financial support from outside sources will be sufficient to support the Company to meet the cash requirements to fund planned operations and other commitments for at least the next 12 months.

As further described in Note 18, the Company has been involved in certain legal proceedings in the Cayman Islands and arbitration claims in China against Mr. Yi Zhang, the former chairperson of the Board. An unfavorable outcome in either or both lawsuits may have material adverse effects on the Company’s continuing operations, cash flows and liquidity, and financial position. On May 30, 2024 and June 1, 2024, two entities controlled by Mr. Yi Zhang applied for property preservation to freeze LakeShore Group’s bank deposits, finished goods and property, plant and equipment.

The conditions raise substantial doubt about the Company’s ability to continue as a going concern for the next 12 months. The Company’s CFS were prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments related to the recoverability and classification of the recorded asset amounts and the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

**NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

These CFS and related notes of LakeShore Group were prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). In the opinion of management, all adjustments necessary to present fairly in all material respects the financial position, results of operations and cash flows for all periods presented were made.

***Basis of Consolidation***

The CFS include the financial statements of LakeShore Group and its wholly-owned subsidiaries. All significant intercompany transactions and balances were eliminated in consolidation. The CFS were prepared on a historical cost basis, except for financial assets and financial liabilities which were measured at fair value (“FV”). The functional currency of LakeShore Biopharma and its Hong Kong subsidiary, Cayman Islands subsidiary is the United States dollars (“US$”). The functional currency of LakeShore Biopharma’s Singapore subsidiary is the Singapore dollars (“S$”). The functional currency of LakeShore Biopharma’s Philippines subsidiary is the Philippines peso (“PHP”). The functional currency of HK Yisheng’s PRC subsidiaries is the Chinese Renminbi (“RMB”). The determination of functional currency is based on the criteria of Accounting Standard Codifications (“ASC”) as promulgated by the Financial Accounting Standards Board, ASC 830, Foreign Currency Matters (“ASC 830”). LakeShore Group uses the RMB as its reporting currency.

***Share Consolidation***

On September 27, 2024, LakeShore Group's shareholders approved the resolution to consolidate every ten shares, par value of US$0.00002 each (whether issued or unissued), into one ordinary share, par value of US$0.0002 each (the “Share Consolidation”), such that following the Share Consolidation, the authorized share capital of LakeShore shall be changed from US$50,000 divided into 2,500,000,000 ordinary shares of a par value of US$0.00002 each to US$50,000 divided into 250,000,000 ordinary shares of a par value of US$0.0002 each. The Share Consolidation has been effective since October 1, 2024. Proportionate adjustments were also made to the exercise prices and the number of shares underlying the Company's outstanding equity awards, as applicable, as well as to the number of shares issuable under the Company's equity incentive plans and certain existing agreements. All shares of the Company's common stock, per-share data and related information included in the accompanying consolidated financial statements have been retroactively adjusted as though the Share Consolidation had been effected prior to all periods presented.

***Use of Estimates***

The preparation of the CFS in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the CFS and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these CFS include, but are not limited to, the valuation of LakeShore Group’s convertible redeemable preferred shares and ordinary shares, accrual of stock-based compensation expense, allowance for estimated credit losses and obsolete inventories, useful life of property, plant and equipment, income taxes and uncertain tax positions. Actual amounts could differ from those estimates. Changes in estimates are recorded in the period when they become known. Due to the risks and uncertainties involved in LakeShore Group’s business and evolving market conditions and, given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

***Foreign Currency Translation***

LakeShore Group’s CFS are reported using the RMB. The results of operations and the consolidated statements of cash flows denominated in foreign currency are translated at the average rate of exchange during the reporting period. Assets and liabilities denominated in foreign currencies at the balance sheet date are translated at the applicable rates of exchange in effect at that date. The equity denominated in the functional currency is translated at the historical rate of exchange at the time of capital transaction. Because cash flows are translated based on the average translation rate, amounts related to assets and liabilities reported on the consolidated statements of cash flows will not necessarily agree with changes in the corresponding balances on the consolidated balance sheets. Foreign currency translation adjustments arising from the use of different exchange rates from period to period are included as a separate component of accumulated other comprehensive income included in LakeShore Group’s consolidated statements of changes in shareholders’ deficit. Gains and losses from foreign currency transactions are included in LakeShore Group’s consolidated statements of operations and comprehensive loss.

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The value of RMB against US$ and other currencies may fluctuate and is affected by, among other things, changes in the PRC’s political and economic conditions. The following table outlines the currency exchange rates used in preparing LakeShore Group’s CFS:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | |  |  | **Years Ended March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |
| **Foreign currency** |  | **Balance Sheet** | |  |  | **Balance Sheet** | |  |  | **Profit/Loss** | |  |  | **Profit/Loss** | |  |  | **Profit/Loss** | |  |
| **RMB:1US$** |  |  | 7.0950 |  |  |  | 7.1782 |  |  |  | 6.6100 |  |  |  | 6.9834 |  |  |  | 7.1366 |  |
| **RMB:1S$** |  |  | 5.2762 |  |  |  | 5.3631 |  |  |  | 4.9346 |  |  |  | 5.2261 |  |  |  | 5.3197 |  |
| **RMB:1PHP** |  |  | 0.1286 |  |  |  | 0.1268 |  |  |  | NA |  |  |  | 0.1275 |  |  |  | 0.1277 |  |

***Convenience translation***

Amounts in US$ are presented for the convenience of the reader and translated at US$1.00 to RMB7.1782, representing the central parity rate release of the People’s Bank of China on March 31, 2025. No representation is made that the RMB amounts could have been, or converted, realized or settled into US$ at such rate.

***Cash***

Cash includes cash on hand and demand deposits in accounts maintained with commercial banks. LakeShore Group maintains bank accounts in China. Cash balances in bank accounts in China are not insured by the Federal Deposit Insurance Corporation or other programs.

***Restricted Cash***

Restricted cash balances mainly relate to restrictions imposed on banks as cash deposits for the issuance of letters of credit or asset preservation in litigation. And it is included in the total cash, cash equivalents, and restricted cash in the consolidated statements of cash flows.

***Expected Credit Losses***

On April 1, 2023, LakeShore Group adopted ASC 326, Credit Losses (“ASC 326”), which replaced previously issued guidance regarding the impairment of financial instruments with an expected loss methodology that will result in more timely recognition of credit losses. LakeShore Group used a modified retrospective approach and did not restate the comparable prior periods. The adoption did not have a material impact on the Company’s CFS.

Upon adoption of ASC 326, LakeShore Group maintains an allowance for credit losses in accordance with ASC 326 and records the allowance for credit losses as an offset to assets such as accounts receivable, etc. LakeShore Group assesses collectability by reviewing receivables on a collective basis where similar characteristics exist. In determining the amount of the allowance for credit losses, LakeShore Group considers historical collectability based on past due status, the age of the receivable balances, credit quality of customers based on ongoing credit evaluations, current economic conditions, reasonable and supportable forecasts of future economic conditions, and other factors that may affect LakeShore Group’s ability to collect from customers. Bad debts are written off as incurred.

***Advance to Suppliers***

Advance to suppliers are amounts advanced to vendors or suppliers for providing raw materials to LakeShore Group. The suppliers usually require advance payments when LakeShore Group orders materials and the advance will be utilized to offset LakeShore Group’s actual payment obligations. These amounts advanced are unsecured, non-interest bearing and generally short term in nature. LakeShore Group reviews its advance to suppliers on a regular basis to determine if the allowance is adequate, and adjusts the allowance when necessary. LakeShore Group recorded RMB2,724,906 and nil allowance against its advance to suppliers as of March 31, 2024 and 2025.

***Inventories***

Inventories are stated at the lower of cost or net realizable value. Cost is determined on the weighted average basis and comprises all cost of purchase and other costs incurred in bringing the inventories to their present location and condition.

LakeShore Group reviews the carrying amounts of the inventories on a quarterly basis to determine if the inventories are carried at lower of cost or net realizable value. The net realizable value is estimated based on current market conditions and historical experience.

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Adjustments are recorded to write down the cost of inventory based on evaluation of, among other things, the expiration date of raw materials and the estimate of future usage, and the likelihood of receiving approval from the CDC (centers for food and drug control) to sell the finished goods . Write-downs are recorded as impairment loss on inventory in the consolidated statements of operations and comprehensive loss. Write-off of inventories during the production process due to damage or destruction are recorded in cost of revenues in the consolidated statements of operations and comprehensive loss.

***Property, Plant and Equipment***

Property, plant and equipment are stated at cost less accumulated depreciation and any impairment losses. The cost 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, are expensed when incurred. In situations where the recognition criteria are satisfied, the expenditure for a major reconstruction is capitalized as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, LakeShore Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to reduce the cost of each item of property, plant and equipment to its residual value over its estimated useful life.

|  |  |  |
| --- | --- | --- |
| **Category** |  | **Estimated useful life** |
| Plant and buildings |  | 6-20 years |
| Machinery and equipment |  | 5-10 years |
| Electronic equipment |  | 3-10 years |
| Office equipment and furniture |  | 3-7 years |
| Motor vehicles |  | 4-5 years |
| Leasehold improvements |  | Lesser of the lease term or life of assets |

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 quarter end.

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 operations in the period the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

***Intangible assets***

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the FV 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 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 is reviewed for appropriateness at each financial year end.

Intangible assets with indefinite useful lives or not yet available for use are tested for impairment annually either individually or at the cash-generating unit level. Such intangible assets, including vaccine license and patent with indefinite useful lives, are not amortized. The useful life of an intangible asset with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

Patents with definite useful lives are stated at cost less any impairment losses and are amortized on the straight-line basis over their estimated useful lives of 15 years. Software and laboratory information system are amortized on the straight-line basis over their estimated useful lives of 10 years.

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An intangible asset that is determined to have an indefinite useful life is not amortized until its useful life is determined to be no longer indefinite. Management evaluates the remaining useful life of an intangible asset that is not being amortized in each reporting period to determine whether events and circumstances continue to support an indefinite useful life. Indefinite-lived intangible assets are subject to impairment testing at least annually.

Management believes that LakeShore Group’s Drug Manufacturing License that was granted by the Liaoning Food and Drug Administration (“FDA”) is an intangible asset with an indefinite useful life because the certificate may be renewed indefinitely at little cost and has historically been renewed by Liaoning Yisheng. Liaoning Yisheng intends to renew the certificate indefinitely, and has the ability to do so. Cash flows from the certificate are expected to continue indefinitely. Therefore, the Drug Manufacturing License is not amortized until its estimated useful life is believed to be no longer indefinite.

Management believes that LakeShore Group’s IPR&D Technologies -PlKA Therapeutic Hepatitis B Vaccines that acquired by LakeShore Group is an intangible asset with an indefinite useful life because the IPR&D is technologies.

All research and development costs are expensed as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when LakeShore 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 expenditures which do not meet these criteria are expensed when incurred.

Land use rights: Land lease payments are amounts paid for the rights to use land in the PRC and are recorded net of accumulated amortization. Amortization is provided on a straight-line basis over the term of the lease agreement, which ranges from 48.75 to 50 years.

***Impairment of Long-lived Assets***

LakeShore Group reviews long-lived assets, including definitive-lived intangible assets and property, plant and equipment, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. When such events occur, LakeShore Group assesses the recoverability of the asset group based on the undiscounted future cash flows the asset group is expected to generate and recognizes an impairment loss when estimated undiscounted future cash flows expected to result from the use of the asset group plus net proceeds expected from disposition of the asset group, if any, is less than the carrying value of the asset group. If LakeShore Group identifies an impairment, LakeShore Group reduces the carrying amount of the asset group to its estimated FV based on a discounted cash flow approach or, when available and appropriate, to comparable market values and the impairment loss, if any, is recognized as impairment loss in the consolidated statements of operations. LakeShore Group uses estimates and judgments in its impairment tests and if different estimates or judgments had been utilized, the timing or the amount of any impairment charges could be different. Asset groups to be disposed of would be reported at the lower of the carrying amount or FV less costs to sell, and they are no longer depreciated. Impairment was recorded in impairment loss on inventory, property, plant and equipment and other assets on the consolidated statements of operations and comprehensive loss.

***Concentrations of Credit Risk and Significant Suppliers***

Financial instruments that potentially subject LakeShore Group to concentration of credit risk consist of cash. LakeShore Group mitigates this risk by maintaining its cash with high quality, accredited financial institutions. As of March 31, 2025, LakeShore Group’s cash was deposited at more than two financial institutions and it did not have any foreign currency exchange contracts, option contracts or other hedging arrangements. LakeShore Group has not experienced any losses on its deposits of cash and does not believe that it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

LakeShore Group’s sales are made primarily to Centers for Disease Control and Prevention (“CDCs”) in China. LakeShore Group does not have a concentration of its revenue and accounts receivable with specific customers. As of March 31, 2025 and 2024, there was no customer which accounted for more than 10% of LakeShore Group’s accounts receivable balance. During the years ended March 31, 2025, 2024 and 2023, there were no customers that accounted for more than 10% of LakeShore Group’s net revenues.

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Details of LakeShore Group’s top 5 vendors accounting for total purchases are as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Year Ended March 31, 2025** | | | | | | | | | |  |
|  |  | **(RMB)** | |  |  | **(US$)** | |  |  |  | |  |
| Vendor D |  |  | 10,580,000 |  |  | $ | 1,473,907 |  |  |  | 16.6 | % |
| Vendor A |  |  | 9,428,000 |  |  |  | 1,313,421 |  |  |  | 14.8 | % |
| Vendor C |  |  | 7,383,664 |  |  |  | 1,028,623 |  |  |  | 11.6 | % |
| Vendor I |  |  | 4,678,400 |  |  |  | 651,751 |  |  |  | 7.4 | % |
| Vendor B |  |  | 3,218,850 |  |  |  | 448,420 |  |  |  | 5.1 | % |
| Total |  |  | **35,288,914** |  |  | **$** | **4,916,122** |  |  |  | **55.5** | **%** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Year Ended March 31, 2024** | | | | | | | | | |  |
|  |  | **(RMB)** | |  |  | **(US$)** | |  |  |  | |  |
| Vendor D |  |  | 36,567,150 |  |  | $ | 5,153,932 |  |  |  | 20.2 | % |
| Vendor I |  |  | 19,635,180 |  |  |  | 2,767,467 |  |  |  | 10.8 | % |
| Vendor C |  |  | 13,260,918 |  |  |  | 1,869,051 |  |  |  | 7.3 | % |
| Vendor E |  |  | 10,090,875 |  |  |  | 1,422,252 |  |  |  | 5.6 | % |
| Vendor G |  |  | 9,544,080 |  |  |  | 1,345,184 |  |  |  | 5.3 | % |
| **Total** |  |  | **89,098,203** |  |  | **$** | **12,557,886** |  |  |  | **49.2** | **%** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Year Ended March 31, 2023** | | | | | | | | | |  |
|  |  | **(RMB)** | |  |  | **(US$)** | |  |  |  | |  |
| Vendor A |  |  | 48,006,500 |  |  | $ | 6,986,117 |  |  |  | 37.9 | % |
| Vendor F |  |  | 15,178,020 |  |  |  | 2,208,772 |  |  |  | 12.0 | % |
| Vendor G |  |  | 10,053,600 |  |  |  | 1,463,044 |  |  |  | 7.9 | % |
| Vendor H |  |  | 6,846,214 |  |  |  | 996,291 |  |  |  | 5.4 | % |
| Vendor C |  |  | 4,746,530 |  |  |  | 690,736 |  |  |  | 3.7 | % |
| **Total** |  |  | **84,830,864** |  |  | **$** | **12,344,960** |  |  |  | **66.9** | **%** |

Details of of LakeShore Group’s key vendors accounting for accounts payable are as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31, 2025** | | | | | | | | | |  |
|  |  | **(RMB)** | |  |  | **(US$)** | |  |  |  | |  |
| Vendor B |  |  | 1,631,850 |  |  | $ | 227,334 |  |  |  | 3.3 | % |
| Vendor A |  |  | 973,250 |  |  |  | 135,584 |  |  |  | 2.0 | % |
| Vendor D |  |  | 624,500 |  |  |  | 87,000 |  |  |  | 1.3 | % |
| Total |  |  | **3,229,600** |  |  | **$** | **449,918** |  |  |  | **6.6** | **%** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31, 2024** | | | | | | | | | |  |
|  |  | **(RMB)** | |  |  | **(US$)** | |  |  |  | |  |
| Vendor D |  |  | 3,408,375 |  |  | $ | 480,391 |  |  |  | 5.0 | % |
| **Total** |  |  | **3,408,375** |  |  | **$** | **480,391** |  |  |  | **5.0** | **%** |

F-14

***Fair Value Measurements***

ASC 825- 10 requires certain disclosures regarding the FV of financial instruments. FV is defined as 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. A three-level FV hierarchy prioritizes the inputs used to measure FV. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure FV are as follows:

|  |  |  |
| --- | --- | --- |
|  | ● | Level 1 - inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets. |

|  |  |  |
| --- | --- | --- |
|  | ● | Level 2 - inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, quoted market prices for identical or similar assets in markets that are not active, inputs other than quoted prices that are observable and inputs derived from or corroborated by observable market data. |

|  |  |  |
| --- | --- | --- |
|  | ● | Level 3 - inputs to the valuation methodology are unobservable. |

The Company’s financial assets and liabilities consist principally of cash, accounts receivable, amounts due from related parties, and other current assets, short-term bank loans and other loans, accounts payable, warrant liabilities, accrued expenses and other current liabilities. The warrant liabilities are classified as Level 3 using a Binomial Option Pricing Model. As of March 31, 2025, the respective carrying values of financial assets and liabilities except for warrants liabilities approximated their fair values due to their short-term maturities.

LakeShore Group’s non-financial assets, such as property, plant and equipment would be measured at FV only if they were determined to be impaired.

***Social Security Insurance***

Employees of LakeShore Group’s subsidiaries that operate in the PRC are required to participate in a pension scheme operated by the local municipal government. According to the Social Insurance Law of the PRC (the “Social Security Insurance Law”) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) that became effective on December 29, 2018, there are five basic types of social security insurance, which include: basic pension, basic medical, unemployment, work-related injury and maternity insurance (collectively known as “social security insurance”). Both employees and employers make contributions for the first three kinds of social security insurance; and only employers make contributions for the latter two kinds, which means the employers must pay all or a portion of the social security insurance premiums for their employees. If the LakeShore Group does not fully comply with the relevant requirements and does not make social insurance contributions in full to the social insurance scheme for the employees of PRC affiliated entities, the LakeShore Group will be required to make up the social insurance contributions as well as to pay late fees at 0.05% per day of the outstanding amount from the due date. If the LakeShore Group fails to make up for the shortfalls within the prescribed time limit, the relevant administrative authorities could impose a fine of one to three times the outstanding amount and file applications to competent courts for compulsory enforcement of payment and deposit. No fine or compulsory enforcement had been imposed by relevant authorities in connection with the delayed payment of the social security insurance premiums by the LakeShore Group. As of March 31, 2025, 2024 and 2023, LakeShore Group’s recorded late fees of RMB11.1 million, RMB10.7 million and RMB9.9 million, respectively, for its liabilities related to social security insurance.

***Leases***

Under ASC Topic 842, Leases (“ASC 842”), LakeShore Group determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, LakeShore Group does not recognize a right-of-use (“ROU”) asset or lease liability. LakeShore Group’s operating leases are recognized on its consolidated balance sheets as noncurrent assets, current liabilities and noncurrent liabilities.

ROU assets are LakeShore Group’s right to use an underlying asset for the lease term and lease liabilities represent LakeShore Group’s obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As LakeShore Group’s leases typically do not provide an implicit rate, LakeShore Group uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The lease terms may include options to extend or terminate the lease when it is reasonably certain that LakeShore Group will exercise that option. Lease expense is recognized on a straight-line basis over the lease term. For leases with terms greater than 12 months, LakeShore Group records the related asset and lease liability at the present value of lease payments over the lease term. For leases with terms less than 12 months, LakeShore Group records rents in administrative expenses.

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***Government Grants***

Government grants are primarily subsidies received from PRC governments for operating a business in their jurisdictions and in compliance with specific policies promoted by the government authorities. LakeShore Group’s PRC-based subsidiaries received specific subsidies and other subsidies from certain local governments. Specific subsidies are subsidies the local government has set certain conditions for the subsidies. Other subsidies are subsidies the local government has not set any conditions and are not tied to future trends or performance of LakeShore Group, receipt of such subsidy is not contingent upon any further actions or performance of LakeShore Group and the amounts do not have to be refunded under any circumstances. Specific subsidies are recorded as deferred government grants upon receipt and are recognized as government grants when the conditions are met. Other subsidies are recognized as government grants upon receipt as further performance by LakeShore Group is not required.

Government grants for R&D are recognized as government grants in the period when the conditions are met after the expenses are incurred. Government grants for property, plant and equipment are deferred and recognized as government grants in the same manner as the property, plant and equipment are depreciated.

***Warrants***

LakeShore Group accounts for warrants as either equity-method or liability-method instruments based on an assessment of the warrant’s specific terms and applicable authoritative guidance in ASC 480 and ASC 815. Warrants recorded as equity are recorded at their relative FV determined at the issuance date and remeasurement is not required. Warrants recorded as liabilities are recorded at their FV, within warrant liabilities on the consolidated balance sheets and are remeasured on each reporting date with changes recorded in FV changes of warrant liabilities on the consolidated statements of operations and comprehensive loss.

Upon the consummation of the Business Combination, each Warrant outstanding immediately prior had ceased to be a warrant with respect to Summit Public Shares and was assumed by LakeShore Biopharma and converted into a LakeShore Biopharma Warrant entitling the holder thereof to purchase such number of Ordinary Share on a one-on-one basis. After the merger with Summit, the Company accounted for the 10,750,000 public warrants as equity and 6,000,000 private warrants as liabilities. LakeShore Biopharma completed a 1-for-10 reverse stock split in October 2024, each warrant became exercisable for 0.1 share of common stock.

***Revenue from Contracts with Customers***

LakeShore Group follows ASC 606 - “Revenue from Contracts with Customers” for all periods presented. ASC 606 established principles for reporting information about the nature, amount, timing, and uncertainty of revenue and cash flows arising from our contracts to provide services to customers. Based on the following five steps analysis, revenues from contracts with customers are recognized when control of the promised goods or services is transferred to the customers, in an amount that reflects the consideration LakeShore Group expects to be entitled in exchange for those goods or services.

Step 1: Identify the contract with the customer;

Step 2: Identify the performance obligations in the contract;

Step 3: Determine the transaction price;

Step 4: Allocate the transaction price to the performance obligations in the contract; and

Step 5: Recognize revenue when LakeShore Group satisfies a performance obligation

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LakeShore Group is principally engaged in the research, development, manufacturing and sale of vaccines and therapeutic biologics. LakeShore Group’s revenues primarily streams from the sales of vaccines.

The core principle underlying the revenue recognition ASC 606 is that LakeShore Group recognizes revenue to represent the transfer of vaccines to customers in an amount that reflects the consideration to which LakeShore Group expects to be entitled in such exchange. This requires LakeShore Group to identify contractual performance obligations and determine whether revenue should be recognized at a point in time or over time. LakeShore Group’s sales contracts of vaccines have one single performance obligation that is to sell vaccines to the customers. The sales contracts with customers do not involve variable considerations, such as discounts and rebates. And according to the historical operation, circumstance of discounts and rebates have never occurred. The customer pays after acceptance of the vaccines. According to ASC 606, the relevant revenue recognition is based on a point in time of customer acceptance confirmation.

In accordance with ASC606-10-55-36 through 55-40, LakeShore Group evaluates whether it is appropriate to record the gross amount of vaccines and related costs or the net amount earned as commissions. When the entity is a principal, that the entity obtains control of the specified goods or services before they are transferred to the customers, the revenues should be recognized in the gross amount of consideration to which it expects to be entitled in exchange for the specified goods or services transferred. When the entity is an agent and its obligation is to facilitate third parties in fulfilling their performance obligation for specified goods or services, the revenues should be recognized in the net amount for the amount of commission which the entity earns in exchange for arranging for the specified goods or services to be provided by other parties. Revenues are recorded net of value-added taxes. LakeShore Group sells vaccines to the customers, and it obtains control of the vaccines before customer acceptance confirmation. Therefore, LakeShore Group is a principal, and the revenues should be recognized according to the gross method.

***Cost of Revenues***

Cost of revenues consists primarily of the cost of merchandise sold and write-down of inventories during the production process due to damage or destruction.

***General and Administrative Expenses***

General and administrative expenses consist mainly of payroll and related costs for employees involved in general corporate functions, including accounting, finance, tax, legal and human resources, professional fees and other general corporate expenses as well as costs associated with the use by these functions of facilities and equipment, such as depreciation and rental expenses.

***Selling and Marketing Expenses***

Selling and marketing expenses consist mainly of payroll and benefits for employees involved in the sales and distribution functions, meeting/event fees, promotion fees, marketing and selling expenses that are related to events and activities at LakeShore Group’s service centers designed to promote product sales as well as operating expenses related to the service centers.

***Research and Development Expenses***

Research and development expenses include costs directly attributable to the conduct of research and development projects, primarily consist of salaries and other employee benefits, testing and clinical trial expenses, consulting service fees, depreciation and amortization, and office and leasing expenses. All costs associated with research and development are expensed as incurred.

F-17

***Other Income (Expenses)***

Other income (expenses) consists of miscellaneous income and expenses not directly related to LakeShore Group’s core business operations. Other income primarily consists of recovery of previously written-off accounts receivable, and write-off of payment obligations that are either more than three years old or no longer justifiable. Other expenses primarily consist of late fees related to LakeShore Group’s income tax and social security insurance payment obligations, charitable donation, medical waste disposal fee and financial expenses.

From December 2013 to June 2019, because LakeShore Group was undergoing the construction and certification process of new manufacturing plant, LakeShore Group didn’t produce and market its rabies vaccine and did not pay any income taxes nor social security insurance for its employees. It accounts for late fees as disclosed in the statements of operations.

***Income Taxes***

**Cayman Islands.** Under the current laws of the Cayman Islands, LakeShore Group is not subject to tax on income or capital gains. In addition, upon payments of dividends by LakeShore Group to its shareholders, no Cayman Islands withholding tax is imposed.

**Hong Kong.** Under the Hong Kong tax laws, HK Yisheng is exempted from profit tax on its foreign-sourced income and there are no withholding taxes in Hong Kong on remittance of dividends.

**Singapore.** The subsidiary incorporated in Singapore files separate income tax returns in Singapore and pays Singapore statutory income tax of 17%.

**China.** Pursuant to the PRC Corporate Income Tax Law and the respective regulations, subsidiaries operating in China are subject to corporate income tax at 25% on the taxable income.

**United States.** The subsidiary incorporated in Maryland, United States is subject to statutory United States federal corporate income tax at 21% and state income tax in Maryland at 8.25%.

**Philippines.** The subsidiary incorporated in Philippines is subject to income tax rate at 20%.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which LakeShore Group operates.

Deferred tax is provided, using the liability method in accordance with ASC740, *Income Taxes* (“ASC 740”), on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

|  |  |  |
| --- | --- | --- |
|  | ● | when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and |

|  |  |  |
| --- | --- | --- |
|  | ● | in respect of taxable temporary differences associated with investments in subsidiaries 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. |

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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:

|  |  |  |
| --- | --- | --- |
|  | ● | when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and |

|  |  |  |
| --- | --- | --- |
|  | ● | in respect of deductible temporary differences associated with investments in subsidiaries, 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 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.

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 Relevant Periods.

Deferred tax assets and liabilities are offset if and only if LakeShore 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.

LakeShore Group records a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more-likely-than-not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in tax expense in the period that includes the enactment date of the change in tax rate.

LakeShore Group accounted for uncertainties in income taxes in accordance with ASC 740. Interest and penalties arising from underpayment of income taxes shall be computed in accordance with the related PRC tax law. The amount of interest expense is computed by applying the applicable statutory rate of interest to the difference between the tax position recognized and the amount previously taken or expected to be taken in a tax return. Interest and penalties recognized in accordance with ASC 740 are classified in the consolidated statements of comprehensive loss as non-operating expense.

***Value Added Tax***

Value-added taxes (“VAT”) collected from customers for product sales and remitted to governmental authorities are presented on a net basis. VAT collected from customers is excluded from revenue. The VAT payable is presented in the account of accrued expenses and other liabilities.

***Taxes other than Income Tax***

Under the PRC Tax Law, taxes other than income tax primarily include additional tax calculated based on value-added tax payable, individual income tax, property tax, etc.

***Share-based Compensation***

LakeShore Group has a share option scheme to provide incentives and rewards to eligible participants. Employees (including directors) of Company receive granted shares and share options in the form of share-based payments, whereby employees render services as consideration for equity instruments (“equity-settled transactions”).

F-19

The cost of equity-settled transactions with employees for grants is measured by reference to the FV of the equity instruments at the date when they are granted. The FV is determined by an external valuer using a binomial model. The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled.

The cumulative expense recognized for equity-settled transactions at the end of each of the relevant periods until the vesting date reflects the extent to which the vesting period has expired and LakeShore 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 FV of awards, but the likelihood of the conditions being met is assessed as part of the LakeShore Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date FV. 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 FV 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.

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. This includes any award where non-vesting conditions within the control of either the LakeShore Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph. When an equity-settled award is surrendered, any expense recognized for the award is reversed immediately.

***Comprehensive Loss***

Comprehensive loss consists of two components, net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of foreign currency translation adjustment from certain subsidiaries of LakeShore Biopharma with a functional currency other than RMB.

***Loss Per Share***

In accordance with ASC 260, Earnings Per Share, basic loss per share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is calculated by dividing net loss attributable to ordinary shareholders as adjusted for the effect of dilutive ordinary equivalent shares, if any, by the weighted average number of ordinary shares plus dilutive equivalent shares outstanding during the period. Dilutive equivalent shares are excluded from the computation of diluted loss per share if their effects would be anti-dilutive. No potential common shares were included in the computation of diluted loss per share when a loss from continuing operations exists.

***Segment Reporting***

ASC 280, “Segment Reporting”, establishes standards for reporting information about operating segments on a basis consistent with LakeShore Group’s internal organizational structure as well as information about geographical areas, business segments and major customers in the CFS for details on LakeShore Group’s business segments.

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LakeShore Group uses the management approach to determine reportable operating segments. The management approach considers the internal organization and reporting used by LakeShore Group’s chief operating decision maker (“CODM”) for making decisions, allocating resources and assessing performance. LakeShore Group’s CODM has been identified as the CEO, who reviews consolidated results when making decisions about allocating resources and assessing performance of LakeShore Group.

Based on management’s assessment, LakeShore Group has only one operating segment, which is the development, production, marketing and sale of biopharmaceutical products. No operating segments were aggregated to form the reportable operating segment.

***Significant Risks***

*Currency risk*

A majority of LakeShore Group’s expenses are denominated in RMB and a significant portion of LakeShore Group and its subsidiaries’ assets and liabilities are denominated in RMB. RMB is not freely convertible into foreign currencies. In the PRC, certain foreign exchange transactions are required by law to be transacted only by authorized financial institutions at exchange rates set by the People’s Bank of China (“PBOC”). Remittances in currencies other than RMB by LakeShore Group in China must be processed through the PBOC or other Company foreign exchange regulatory bodies which require certain supporting documentation in order to affect the remittance.

LakeShore Group maintains bank accounts in the PRC. On May 1, 2015, China’s new Deposit Insurance Regulation came into effect, pursuant to which banking financial institutions, such as commercial banks, established in the PRC are required to purchase deposit insurance for deposits in RMB and in foreign currency placed with them. Such Deposit Insurance Regulation would not be effective in providing complete protection for LakeShore Group’s accounts, as its aggregate deposits are higher than the compensation limit, which is RMB500,000 ($69,655) for one bank. However, LakeShore Group believes the risk of failure of any of these Chinese banks is remote. Bank failure is uncommon in the PRC and LakeShore Group believes that those Chinese banks that hold LakeShore Group’s cash are financially sound based on public available information.

*Concentration and political risk*

Currently, LakeShore Group has significant operations in the PRC. Accordingly, LakeShore Group’s business, financial condition and results of operations may be influenced by the political, economic and legal environment in the PRC, and by the general state of the PRC’s economy. LakeShore Group’s operations in the PRC are subject to specific considerations and significant risks not typically associated with companies in North America and Western Europe. LakeShore Group’s results may be adversely affected by changes in governmental policies in laws and regulations, anti-inflationary measures, currency conversion and remittance abroad, and rates and methods of taxation, among other things. Although LakeShore Group has not experienced losses from these situations and believes it is in compliance with existing laws, this may not be indicative of future results.

*Interest rate risk*

Fluctuations in interest rates may negatively affect LakeShore Group’s financial condition and results of operations. LakeShore Group is exposed to floating interest rate risk on cash deposit and floating rate borrowings, and the risks due to changes in interest rates is not material. LakeShore Group has not used any derivative financial instruments to manage LakeShore Group’s interest risk exposure.

***Related Parties***

A party is considered related to LakeShore Group if the party directly or indirectly or through one or more intermediaries, controls, is controlled by, or is under common control with LakeShore Group. Related parties also include principal owners of LakeShore Group, its management, members of the immediate families of principal owners of LakeShore Group and its management and other parties with which LakeShore Group may deal if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests. A party which can significantly influence the management or operating policies of the transacting parties or if it has an ownership interest in one of the transacting parties and can significantly influence the other to an extent that one or more of the transacting parties might be prevented from fully pursuing its own separate interests is also a related party.

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***Recently Adopted Accounting Pronouncements***

*Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures:* In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07 which requires incremental reportable segment disclosures. The new standard requires that a public entity disclose significant segment expenses, the title and position of the CODM, and how the CODM uses the reported measures in assessing performance and deciding how to allocate resources. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. This ASU does not have a significant impact on the consolidated financial statements.

***Recently Issued Accounting Pronouncements***

*Income Taxes (Topic 740), Improvements to Income Tax Disclosures:* In December 2023, the FASB issued ASU 2023-09, which requires disaggregated information about a reporting entity’s effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company’s management is evaluating the impact this guidance will have on its consolidated financial statements and disclosures.

*Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses:* In November 2024, the FASB issued ASU 2024-03 which requires disaggregated information about a public business entity’s expenses to provide more detailed information about the types of expenses in commonly presented expense captions (such as cost of sales, SG&A, and research and development). In January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU No. 2024-03. ASU 2024-03 is effective for public business entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company’s management is evaluating the impact this guidance will have on its consolidated financial statements and disclosures.

**NOTE 4 – ACCOUNTS RECEIVABLE**

Accounts receivable are as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Trade receivables |  |  | 473,515,321 |  |  |  | 531,234,070 |  |  |  | 74,006,585 |  |
| Allowance for expected credit losses |  |  | (29,354,030 | ) |  |  | (30,317,255 | ) |  |  | (4,223,518 | ) |
| **Accounts receivable** |  |  | **444,161,291** |  |  |  | **500,916,815** |  |  |  | **69,783,067** |  |

The allowance for expected credit losses reflects LakeShore Group’s best estimate of probable losses inherent in the accounts receivable balance. In determining the amount of the allowance for credit losses, LakeShore Group considers historical collectability based on past due status, the age of the receivable balances, credit quality of customers based on ongoing credit evaluations, current economic conditions, reasonable and supportable forecasts of future economic conditions, and other factors that may affect LakeShore Group’s ability to collect from customers. Bad debts are written off as incurred. During the years ended March 31, 2023, 2024 and 2025, LakeShore Group’s accounts receivable had been written off of nil, nil,RMB1.9 million.

Below is an analysis of the movements in the allowance for expected credit losses:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Year Ended March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Balance at beginning of the year |  |  | 24,366,824 |  |  |  | 29,354,030 |  |  | $ | 4,089,330 |  |
| Additions |  |  | 4,987,206 |  |  |  | 2,890,210 |  |  |  | 402,638 |  |
| Write off |  |  | - |  |  |  | (1,926,985 | ) |  |  | (268,450 | ) |
| **Balance at end of the year** |  |  | **29,354,030** |  |  |  | **30,317,255** |  |  | **$** | **4,223,518** |  |

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**NOTE 5 – INVENTORIES**

LakeShore Group’s inventories consist of the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Raw materials |  |  | 68,613,919 |  |  |  | 36,617,473 |  |  | $ | 5,101,205 |  |
| Work in progress |  |  | 49,083,445 |  |  |  | 58,114,028 |  |  |  | 8,095,905 |  |
| Finished goods |  |  | 153,879,476 |  |  |  | 163,931,228 |  |  |  | 22,837,374 |  |
| Allowance for inventories |  |  | (68,154,238 | ) |  |  | (31,070,837 | ) |  |  | (4,328,500 | ) |
| **Inventories** |  |  | **203,422,602** |  |  |  | **227,591,892** |  |  | **$** | **31,705,984** |  |

In fiscal 2025, the amount of RMB37.1 million allowance for inventories was written off. In fiscal 2024, allowance recognized on inventories amounted RMB63.4 million.

**NOTE 6 – PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Cost** |  |  | |  |  |  | |  |  |  | |  |
| Construction in progress |  |  | 255,113,837 |  |  |  | 287,877,212 |  |  | $ | 40,104,373 |  |
| Plant and buildings |  |  | 217,248,236 |  |  |  | 226,754,681 |  |  |  | 31,589,351 |  |
| Machinery and equipment |  |  | 255,507,522 |  |  |  | 182,259,864 |  |  |  | 25,390,748 |  |
| Electronic equipment |  |  | 10,335,481 |  |  |  | 10,727,340 |  |  |  | 1,494,433 |  |
| Motor vehicles |  |  | 3,081,506 |  |  |  | 1,909,049 |  |  |  | 265,951 |  |
| Office equipment and furniture |  |  | 42,870,071 |  |  |  | 21,215,986 |  |  |  | 2,955,614 |  |
| Leasehold improvements |  |  | 4,862,781 |  |  |  | 2,392,153 |  |  |  | 333,253 |  |
| **Total Cost** |  |  | **789,019,434** |  |  |  | **733,136,285** |  |  |  | **102,133,723** |  |
| Less: accumulated depreciation |  |  | (205,542,536 | ) |  |  | (191,704,086 | ) |  |  | (26,706,429 | ) |
| Less: asset impairment |  |  | (110,128,892 | ) |  |  | (127,930,754 | ) |  |  | (17,822,122 | ) |
| **Property, plant and equipment** |  |  | **473,348,006** |  |  |  | **413,501,445** |  |  | **$** | **57,605,172** |  |

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In fiscal 2014, based on an evaluation of the Company’s related production plan and the conditions of its property, plant and equipment, the Company recorded an asset impairment for approximately RMB29.9 million on those property, plant and equipment that could no longer be used for production.

In fiscal 2024, based on an evaluation of the Company’s production facilities for PIKA recombinant protein COVID-19 vaccine, the Company recorded an asset impairment of approximately RMB80.2 million on the related property, plant and equipment that could no longer be used for other vaccine production.

In fiscal 2025, based on an evaluation of the Company’s production facilities for PIKA recombinant protein COVID-19 vaccine, the Company recorded an asset impairment of approximately RMB17.8 million on the related property, plant and equipment that could no longer be used for other vaccine production.

**NOTE 7 – PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current asset consist of the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Deposits (1) |  |  | 4,043,044 |  |  |  | 3,283,017 |  |  | $ | 457,359 |  |
| Staff advances (2) |  |  | 174,810 |  |  |  | 300,000 |  |  |  | 41,793 |  |
| Staff’s social security (3) |  |  | 158,872 |  |  |  | 79,907 |  |  |  | 11,132 |  |
| Value added tax recoverable (4) |  |  | 1,598,117 |  |  |  | 768,500 |  |  |  | 107,060 |  |
| Other receivables (5) |  |  | 1,395,246 |  |  |  | 104,939 |  |  |  | 14,620 |  |
| **Total** |  |  | **7,370,089** |  |  |  | **4,536,363** |  |  | **$** | **631,964** |  |

|  |  |
| --- | --- |
| (1) | Deposits primarily are deposits to Zhongguancun Technology Leasing Co., Ltd for the loan. |

|  |  |
| --- | --- |
| (2) | Staff advances primarily are cash advances paid to employees in advance of their expected business travel or in connection with various expense incurred in the ordinary course of business, such as sales and marketing activities. |

|  |  |
| --- | --- |
| (3) | Staff social security primarily are the portion of the government mandated defined contribution plan that should be made by employees. But this portion should be paid to the government by LakeShore Group on behalf of the employees pursuant to PRC labor regulation. When LakeShore Group pays wages to employees, this portion should be deducted accordingly. |

|  |  |
| --- | --- |
| (4) | Value-added taxes (“VAT”) includes input tax on purchase and output tax on sales. VAT collected from customers relating to product sales and remitted to governmental authorities is presented on a net basis, and it is excluded from revenue. LakeShore Group is in a net VAT recoverable position when its input tax on purchase in the current year is greater than the output tax on sales. Such net amount can be deducted in the following years. |

|  |  |
| --- | --- |
| (5) | Other receivables primarily consist of prepayment to third parties, such as freight, water and electricity, and promotion fees. |

**NOTE 8 – INTANGIBLE ASSETS**

LakeShore Group’s intangible assets are presented below:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Cost** |  |  | |  |  |  | |  |  |  | |  |
| Patents |  |  | 79,608,000 |  |  |  | 98,519,825 |  |  | $ | 13,724,865 |  |
| Licenses, software and laboratory information system |  |  | 10,435,478 |  |  |  | 10,614,878 |  |  |  | 1,478,766 |  |
| Land use rights |  |  | 67,181,860 |  |  |  | 67,181,860 |  |  |  | 9,359,151 |  |
| **Total Cost** |  |  | **157,225,338** |  |  |  | **176,316,563** |  |  |  | **24,562,782** |  |
| Less: accumulated amortization |  |  | (85,980,002 | ) |  |  | (93,077,907 | ) |  |  | (12,966,748 | ) |
| Less: asset impairment |  |  | - |  |  |  | (10,384,000 | ) |  |  | (1,446,602 | ) |
| **Intangible assets** |  |  | **71,245,336** |  |  |  | **72,854,656** |  |  | **$** | **10,149,432** |  |

In fiscal 2025, based on an evaluation of the Company’s patent, the Company recorded an asset impairment of approximately RMB10.4 million (US$1.4 million) on the patent which was purchased long time ago.

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**NOTE 9 – BANK LOANS AND OTHER BORROWINGS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |  | **Maturity** |  | **Interest** | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |  | **Date** |  | **Rate** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |  |  |  |  | |  |
| China Guangfa Bank Co., Ltd. Shenyang Branch (1) |  |  | 18,357,574 |  |  |  | - |  |  |  | - |  |  | 2024/9/9 |  |  | 4.00%-4.50 | % |
| Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch (2) |  |  | 44,983,415 |  |  |  | 38,428,803 |  |  |  | 5,353,543 |  |  | 2024/4/12-2025/11/7 |  |  | 4.00 | % |
| China CITIC Bank Shenyang Tiexi Branch (3） |  |  | 12,388,064 |  |  |  | - |  |  |  | - |  |  | 2024/5/29 |  |  | 4.75%-5.00 | % |
| China Construction Bank Shenyang Heping Branch (4） |  |  | 38,990,000 |  |  |  | 4,820,000 |  |  |  | 671,478 |  |  | 2024/7/24-2025/11/14 |  |  | 4.00 | % |
| China Construction Bank Shenyang Heping Branch (5） |  |  | 712,400 |  |  |  | - |  |  |  | - |  |  | 2024/7/19 |  |  | 3.90 | % |
| Zhongguancun Technology Leasing Co., Ltd (6) |  |  | 8,666,664 |  |  |  | 5,777,784 |  |  |  | 804,907 |  |  | 2025/11/7 |  |  | 5.00 | % |
| China CITIC Bank Shenyang Tiexi Branch (7) |  |  | 1,400,000 |  |  |  | 5,503,290 |  |  |  | 766,667 |  |  | 2024/5/15-2025/11/15 |  |  | 4.55 | % |
| China CITIC Bank Shenyang Tiexi Branch (8) |  |  | 900,000 |  |  |  | 3,618,982 |  |  |  | 504,163 |  |  | 2024/7/8-2026/1/18 |  |  | 4.55 | % |
| China CITIC Bank Shenyang Tiexi Branch (9) |  |  | 880,000 |  |  |  | 3,503,099 |  |  |  | 488,019 |  |  | 2024/7/18-2026/1/18 |  |  | 4.55 | % |
| Industrial Bank Shenyang Branch (10) |  |  | 29,776,670 |  |  |  | - |  |  |  | - |  |  | 2024/8/15-2024/9/17 |  |  | 4.00 | % |
| R-Bridge Healthcare Fund, LP (11) |  |  | 118,354,060 |  |  |  | - |  |  |  | - |  |  | 2026/9/15 |  |  | 4.00 | % |
| Minsheng Bank Shenyang Huanghe Street Branch (12) |  |  | 29,990,032 |  |  |  | - |  |  |  | - |  |  | 2024/7/7-2025/1/16 |  |  | 4.00 | % |
| CITIC Financial Leasing Co., Ltd (14) |  |  | 13,141,853 |  |  |  | 13,797,406 |  |  |  | 1,922,126 |  |  | 2026/5/29 |  |  | 4.80 | % |
| Beijing Huarui Jingkai Real Estate Co., Ltd(15) |  |  | - |  |  |  | 311,401,631 |  |  |  | 43,381,576 |  |  | 2025/12/31 |  |  | 5.00 | % |
| Apex Prospect Limited（16） |  |  | - |  |  |  | 3,589,100 |  |  |  | 500,000 |  |  | 2026/2/17 |  |  | 5.00 | % |
| **Bank loans and other borrowings due within one year** |  |  | **318,540,732** |  |  |  | **390,440,095** |  |  |  | **54,392,479** |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| China Construction Bank Shenyang Heping Branch (4) |  |  | 4,820,000 |  |  |  | - |  |  |  | - |  |  | 2025/10/15-2025/11/14 |  |  | 4.00 | % |
| Zhongguancun Technology Leasing Co., Ltd (6) |  |  | 5,777,784 |  |  |  | - |  |  |  | - |  |  | 2025/11/7 |  |  | 5.00 | % |
| Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch (2) |  |  | 38,428,802 |  |  |  | - |  |  |  | - |  |  | 2025/4/12-2025/11/7 |  |  | 4.00 | % |
| China CITIC Bank Shenyang Tiexi Branch (7) |  |  | 5,503,290 |  |  |  | - |  |  |  | - |  |  | 2025/5/15-2025/11/15 |  |  | 4.55 | % |
| China CITIC Bank Shenyang Tiexi Branch (8) |  |  | 3,618,982 |  |  |  | - |  |  |  | - |  |  | 2025/7/8-2026/1/18 |  |  | 4.55 | % |
| China CITIC Bank Shenyang Tiexi Branch (9) |  |  | 3,503,099 |  |  |  | - |  |  |  | - |  |  | 2025/7/18-2026/1/18 |  |  | 4.55 | % |
| Industrial Bank Shenyang Branch (13) |  |  | 19,993,041 |  |  |  | 19,993,041 |  |  |  | 2,785,244 |  |  | 2026/7/31-2026/9/3 |  |  | 4.25 | % |
| CITIC Financial Leasing Co., Ltd (14) |  |  | 17,338,782 |  |  |  | 3,510,430 |  |  |  | 489,041 |  |  | 2026/5/29 |  |  | 4.80 | % |
| **Long-term bank loans and other borrowings** |  |  | **98,983,780** |  |  |  | **23,503,471** |  |  |  | **3,274,285** |  |  |  |  |  |  |  |
| **Total bank loans and other borrowings** |  |  | **417,524,512** |  |  |  | **413,943,566** |  |  |  | **57,666,764** |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| (1) | On September 13, 2021, LakeShore Group entered into a credit facility of RMB100.0 million with China Guangfa Bank Co., Ltd. Shenyang Branch for three years to finance our working capital requirements. LakeShore Group drew RMB19.8 million from April 18, 2024 to May 17, 2024, with interest at 4%-4.5%, which was due on September 10, 2024. On September 9, 2024, LakeShore Group repaid RMB38.2 million. As of March 31, 2025, LakeShore Group has repaid it fully. |

|  |  |
| --- | --- |
| (2) | On July 12, 2021, LakeShore Group entered into a credit facility of RMB140.0 million with Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch for three years to finance its working capital requirements. On September 12, 2023, LakeShore Group entered into another credit facility of RMB85.0 million with Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch for three years to finance its working capital requirements. From April 12, 2024 to March 20, 2025, LakeShore Group repaid RMB45.0 million. As of March 31, 2025, the balance of RMB38.4 million (US$5.4 million) was outstanding. |

|  |  |
| --- | --- |
| (3) | On January 13, 2023, LakeShore Group entered into a credit facility of RMB40.0 million with China CITIC Bank Shenyang Tiexi Branch, due on May 29, 2024, to finance its working capital requirements. On May 29, 2024, LakeShore Group repaid RMB12.4 million. As of March 31, 2025, LakeShore Group has repaid it fully. |

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|  |  |
| --- | --- |
| (4) | From March 17, 2023 to November 15, 2023, LakeShore Group borrowed RMB43.8 million in total with interest at 4.00% from China Construction Bank Shenyang Heping Branch. The loan will be due from July 24, 2024 to November 14, 2025. From July 22, 2024 to December 5, 2024, LakeShore Group repaid RMB39.0 million. As of March 31, 2025, the balance of RMB4.8 million (US$0.7 million) was outstanding. |

|  |  |
| --- | --- |
| (5) | On July 20, 2023, LakeShore Group borrowed RMB712,400 with interest at 3.90% from China Construction Bank Shenyang Heping Branch for one year. On July 18, 2024, LakeShore Group repaid RMB712,400. As of March 31, 2025, LakeShore Group has repaid it fully. |

|  |  |
| --- | --- |
| (6) | On November 8, 2022, LakeShore Group borrowed RMB26.0 million with interest at 5.00% from Zhongguancun Technology Leasing Co., Ltd for 36 months. LakeShore Group shall repay RMB722,222 monthly from December 15, 2022 to October 15, 2025 and pay the last repayment of RMB722,230 on November 7, 2025. LakeShore Group repaid RMB11.6 million from December 2022 to March 2024 and 8.7 million from April 2024 to March 2025. As of March 31, 2025, the balance of RMB5.8 million (US$0.8 million) was outstanding. |

|  |  |
| --- | --- |
| (7) | On November 15, 2023, LakeShore Group borrowed RMB6.9 million from China CITIC Bank Shenyang Tiexi Branch to finance working capital requirements, with interest at 4.55%. The loan will be due from May 15, 2024 to November 15, 2025. From May 15, 2024 to November 13, 2024, LakeShore Group repaid RMB1.4 million. As of March 31, 2025, the balance of RMB5.5 million (US$0.8 million) was outstanding. |

|  |  |
| --- | --- |
| (8) | On January 8, 2024, LakeShore Group borrowed RMB4.5 million with interest at 4.55% from China CITIC Bank Shenyang Tiexi Branch to finance working capital requirements. The loan will be due from July 8, 2024 to January 8, 2026. From July 4, 2024 to January 7, 2025, LakeShore Group repaid RMB0.9 million. As of March 31, 2025, the balance of RMB3.6 million (US$0.5 million) was outstanding. |

|  |  |
| --- | --- |
| (9) | On January 18, 2024, LakeShore Group borrowed RMB4.4 million with interest at 4.55% from China CITIC Bank Shenyang Tiexi Branch to finance working capital requirements. The loan will be due from July 18, 2024 to January 18, 2026. From July 17, 2024 to January 16, 2025, LakeShore Group repaid RMB0.88 million. As of March 31, 2025, the balance of RMB3.5 million (US$0.5 million) was outstanding. |

|  |  |
| --- | --- |
| (10) | From August 16, 2023 to September 18, 2023, LakeShore Group borrowed RMB29.8 million with interest at 4.00% from Industrial Bank Shenyang Branch for one year. The loan will be due from August 15, 2024 to September 17, 2024. From August 14, 2024 to September 13, 2024, LakeShore Group repaid RMB29.8 million. As of March 31, 2025, LakeShore Group has repaid it fully. |

|  |  |
| --- | --- |
| (11) | On March 16, 2022, LakeShore Group entered into a facility agreement with R-Bridge Healthcare Fund, LP (“R-Bridge”), as agent, to finance RMB274,868,000 (US$40,000,000) for 54 months with interest at 4.00% (“R-Bridge Loan”). On December 27, 2023, HK Yisheng received a letter from R-Bridge (the “R-Bridge Letter”), notifying the Company that it has reason to believe HK Yisheng defaulted under financial covenants and other obligations under the facility agreement, and under the instructions of the lenders to urge the Company to consider and reach an amicable solution with the lenders, including, without limitation, repaying the loan of $40.0 million in full, as soon as possible. The Company repaid $15.0 million, $10.0 million and $18.1 million respectively in February, March and April, 2024. As of March 31, 2025, LakeShore Group has repaid its full amount of $40.0 million and accrued interest of $3.1 million. |

|  |  |
| --- | --- |
| (12) | From July 7, 2023 to January 16, 2024, LakeShore Group borrowed RMB30.0 million with interest at 4.0% from Minsheng Bank Shenyang Huanghe Street Branch, due from July 7, 2024 to January 16, 2025. From July 5, 2024 to January 15, 2025, LakeShore Group repaid RMB30.0 million. As of March 31, 2025, LakeShore Group has repaid it fully. |

|  |  |
| --- | --- |
| (13) | From August 14, 2023 to September 14, 2023, LakeShore Group borrowed RMB20.0 million with interest at 4.25% from Industrial Bank Shenyang Branch for about three years. The loan will be due from July 31, 2026 to September 3, 2026. As of March 31, 2025, the balance of RMB20.0 million (US$2.8 million) was outstanding. |

|  |  |
| --- | --- |
| (14) | On May 29, 2023, LakeShore Group borrowed RMB40.0 million with interest at 4.80% from CITIC Financial Leasing Co., Ltd for three years. The loan will be due on May 29, 2026. From August 15, 2023 to February 14, 2025, LakeShore Group repaid RMB22.7 million. As of March 31, 2025, the balance of RMB17.3 million (US$2.4 million) was outstanding, of which RMB13.8 million (US$1.9 million) will become due within one year. |
| (15) | From May 29, 2024 to March 20, 2025, LakeShore Group borrowed RMB311.4 million with interest at 5.0% from Beijing Huarui Jingkai Real Estate Co., Ltd. The loan will be due on December 31, 2025. As of March 31, 2025, the balance of RMB311.4 million (US$43.4 million) was outstanding. |
| (16) | On March 26, 2025, LakeShore Group borrowed RMB3.6 million with interest at 5.0% from Apex Prospect Limited. The loan will be due on February 17, 2026. As of March 31, 2025, the balance of RMB3.6 million (US$0.5 million) was outstanding. |

LakeShore Group recorded RMB16.7 million, RMB47.5 million and RMB32.0 million of interest expense for the years ended March 31, 2025, 2024 and 2023, respectively.

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**NOTE 10 – LEASES**

A summary of LakeShore Group’s operating leases as of March 31, 2025 and 2024 is as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Operating lease ROU assets |  |  | 7,275,367 |  |  |  | 847,331 |  |  | $ | 118,042 |  |
| Operating lease liabilities - current |  |  | 5,156,540 |  |  |  | 457,012 |  |  | $ | 63,667 |  |
| Operating lease liabilities - non-current |  |  | 1,783,593 |  |  |  | - |  |  | $ | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Weighted average remaining lease term |  |  | 1.5 |  |  |  | 0.8 |  |  |  | 0.8 |  |
| Weighted average discount rate |  |  | 4.8 | % |  |  | 7 | % |  |  | 7 | % |

A summary of lease cost recognized in LakeShore Group’s CFS and supplemental cash flow information related to operating leases is as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Operating lease cost |  |  | 5,002,684 |  |  |  | 5,252,026 |  |  |  | 3,306,826 |  |  | $ | 460,676 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash paid for operating leases |  |  | 3,349,856 |  |  |  | 5,272,746 |  |  |  | 2,895,125 |  |  | $ | 403,322 |  |

A summary of maturity of operating lease liabilities under the LakeShore Group’s non-cancelable operating leases as of March 31, 2025 is as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Year Ended March 31,** |  | **(RMB)** | |  |  | **(US$)** | |  |
| 2026 |  |  | 470,319 |  |  | $ | 65,521 |  |
| 2027 |  |  | - |  |  |  | - |  |
| **Total lease payments** |  |  | 470,319 |  |  |  | 65,521 |  |
| Less: Interest |  |  | (13,307 | ) |  |  | (1,854 | ) |
| **Present value of operating lease liabilities** |  |  | 457,012 |  |  | $ | 63,667 |  |

**NOTE 11 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES**

Accrued expenses and other current liabilities consist of the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Salaries and social security insurance (1) |  |  | 59,297,454 |  |  |  | 56,779,828 |  |  | $ | 7,910,037 |  |
| Promotion service fee (2) |  |  | 114,508,487 |  |  |  | 121,699,362 |  |  |  | 16,954,022 |  |
| Taxes other than income tax |  |  | 3,012,548 |  |  |  | 2,799,771 |  |  |  | 390,038 |  |
| Late fees (3) |  |  | 10,683,258 |  |  |  | 11,138,120 |  |  |  | 1,551,659 |  |
| Payable for property, plant and equipment |  |  | 20,413,798 |  |  |  | 13,161,835 |  |  |  | 1,833,584 |  |
| CDC transportation and storage fee |  |  | 53,515,233 |  |  |  | 61,289,585 |  |  |  | 8,538,294 |  |
| Guarantee deposits (4) |  |  | 119,313,398 |  |  |  | 99,886,728 |  |  |  | 13,915,289 |  |
| Professional service fee (5) |  |  | 7,346,813 |  |  |  | 7,406,166 |  |  |  | 1,031,758 |  |
| Interest payable（6） |  |  | 9,909,655 |  |  |  | 3,578,336 |  |  |  | 498,501 |  |
| Other (7) |  |  | 10,737,325 |  |  |  | 5,108,227 |  |  |  | 711,630 |  |
| **Total** |  |  | **408,737,969** |  |  |  | **382,847,958** |  |  | **$** | **53,334,812** |  |

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|  |  |
| --- | --- |
| (1) | This includes unpaid salaries and outstanding social security insurance. During fiscal 2024, LakeShore Group paid approximately RMB14.6 million to reduce its payable for salaries and social security insurance. During fiscal 2025, LakeShore Group paid approximately RMB14.5 million to reduce its payable for salaries and social security insurance. Salaries and social security insurance payables consist of the following: |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Salaries |  |  | 51,990,629 |  |  |  | 50,216,255 |  |  | $ | 6,995,661 |  |
| Social security insurance |  |  | 6,656,034 |  |  |  | 6,372,000 |  |  |  | 887,688 |  |
| Union Fee |  |  | 650,791 |  |  |  | 191,573 |  |  |  | 26,688 |  |
| **Total** |  |  | **59,297,454** |  |  |  | **56,779,828** |  |  | **$** | **7,910,037** |  |

|  |  |
| --- | --- |
| (2) | Promotion service fee primarily represents fees for the vaccine promotion, including design and implementation of academic activities, and collection of market information. |

|  |  |
| --- | --- |
| (3) | Late fees primarily are for corporate income tax, taxes other than income tax and social security insurance and housing reserve fund contributions due to the fact LakeShore Group failed to pay income tax for calendar 2011 to calendar 2013, taxes other than income tax for calendar 2014 to the beginning of calendar 2021 and social security insurance for calendar 2015 to the beginning of calendar 2021. As of June, 2021, LakeShore Group has paid the unpaid taxes, including income tax and other taxes other than income tax, as well as the late fees charge of them. From fiscal 2022, the late fee is incurred for unpaid social insurance. |

|  |  |
| --- | --- |
| (4) | Guarantee deposits primarily are refundable deposits paid to LakeShore Group by external service providers to guarantee the external service providers will provide us with high quality and reasonable professional services. The external service providers’ professional service scope includes conducting market research and analysis, monitoring product clinical information, collecting and reporting adverse events of the product use, providing academic visits and education seminars, assisting product shipment and payment collections. Their services don’t assume inventory risk for the vaccines before they are transferred to the end customers. |

|  |  |
| --- | --- |
| (5) | Professional service fees primarily are from consultants and other advisors. |

|  |  |
| --- | --- |
| (6) | Interest payable primarily includes interest and royalties payable to R-Bridge Healthcare Fund, LP. |

|  |  |
| --- | --- |
| (7) | Others primarily are employees’ reimbursement . |

**NOTE 12 – WARRANTS**

As of March 31, 2025, LakeShore Group has 10,750,000 public warrants and 6,000,000 private warrants.

LakeShore Group accounts for its outstanding warrants in accordance with ASC 815-40-15-7D and 7F. Management determined the private warrants do not meet the criteria for equity treatment and must be recorded as liabilities. Accordingly, LakeShore Group classifies the private warrants as liabilities at their FV and adjusts the private warrants to FV at each reporting period. Management further determined that its public warrants qualify for equity treatment. Warrant liability is subject to re-measurement at each balance sheet date until exercised, and any change in FV is recognized in statements of operations. The private warrants are valued using a Binomial Option Pricing Model.

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Upon the consummation of the business combination, each Summit Warrant outstanding immediately prior ceased to be a warrant with respect to Summit Public Shares and was assumed by LakeShore Biopharma and converted into a LakeShore Biopharma Warrant entitling the holder thereof to purchase such number of Ordinary Share on a one-on-one basis. Each LakeShore Biopharma Warrant will otherwise continue to have and be subject to substantially the same terms and conditions as were applicable to such Summit Warrant immediately prior to the consummation of the Business Combination (including any repurchase rights and cashless exercise provisions). Upon the consummation of the Business Combination with Summit, LakeShore Group has 10,000,000 public and 6,000,000 private warrants.

LakeShore Biopharma completed a 1-for-10 reverse stock split in October 2024, each warrant became exercisable for 0.1 share of common stock.

The private warrants are accounted for as liabilities in accordance with ASC 815-40 and are presented within warrant liabilities on the balance sheets. The warrants were classified as Level 3 at the initial measurement date due to the use of unobservable inputs. The Binomial Option Pricing Model with the following key assumptions is used for estimating the FV of private warrants.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **As of  March 31, 2025(US$)** | |  |
| Fair value of the underlying asset as of the Valuation Date(per 0.1 share) |  | $ | 0.245 |  |
| Strike price |  | $ | 11.5 |  |
| Life to expiration (Years.) |  |  | 3.0 |  |
| Volatility |  |  | 153.8 | % |
| Number of steps |  |  | 100 |  |
| Redemption price (per 0.1 share) |  | $ | 0.1 |  |

As of March 31, 2025, the value of the private warrants was RMB3.4 million. The change in FV from April 1, 2024 to March 31, 2025 was RMB1.1 million. The table below reflects the movement of warrant liabilities for the year ended March 31, 2025:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **April 1, 2024** | |  |  | **Change in fair value** | |  |  | **Foreign currency translation** | |  |  | **March 31, 2025** | |  |  | **March 31, 2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Private Warrants |  |  | 4,548,004 |  |  |  | (1,149,792 | ) |  |  | 46,630 |  |  |  | 3,444,842 |  |  | $ | 479,903 |  |
| **Total** |  |  | **4,548,004** |  |  |  | **(1,149,792** | **)** |  |  | **46,630** |  |  |  | **3,444,842** |  |  | **$** | **479,903** |  |

**NOTE 13 – WARRANTS ACCOUNTED AS EQUITY-METHOD INSTRUMENTS**

Upon consummation of the Business Combination with Summit, Summit’s 10,000,000 public warrants were converted into LakeShore Biopharma warrants, and LakeShore Group sold additional 750,000 public warrants.

Following the Business Combination, LakeShore Biopharma may redeem public warrants prior to their exercise at a time that is disadvantageous to the holders of such warrants, thereby making such warrants worthless. More specifically:

|  |  |  |
| --- | --- | --- |
|  | ● | LakeShore Biopharma can redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at $0.01 per warrant, provided the last reported sales price of LakeShore Biopharma Ordinary Shares equals or exceeds $180.00 per share (as adjusted for capitalization, share dividends, split-up and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to proper notice of such redemption and provided that certain other conditions are met. |

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|  |  |  |
| --- | --- | --- |
|  | ● | LakeShore Biopharma also can redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at $0.10 per warrant upon a minimum of 30 days’ prior written notice of redemption provided that the last reported sales price of LakeShore Biopharma Ordinary Shares equals or exceeds $100.00 per share (as adjusted for capitalization, share dividends, split-up and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to proper notice of such redemption and provided that certain other conditions are met, including that holders of the Warrants will be able to exercise their Warrants prior to redemption for a number of LakeShore Biopharma Ordinary Shares determined based on the redemption date and the fair market value of the LakeShore Biopharma Ordinary Shares. The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the warrants, including because the number of LakeShore Biopharma Ordinary Shares received is capped at 0.0361 LakeShore Biopharma Ordinary Shares per warrant (subject to adjustment) irrespective of the remaining life of the warrants. |

In each case, LakeShore Biopharma may only call the Warrants for redemption upon a minimum of 30 days’ prior notice of redemption.

Redemption of the outstanding Warrants could force holders of the Warrants to (a) exercise Warrants and pay the exercise price therefor at a time when it may be disadvantageous for such holders to do so, (b) sell Warrants at the then-current market price when they might otherwise wish to hold their Warrants or (c) accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of the Warrants.

**NOTE 14 – STOCK-BASED COMPENSATION**

LakeShore Group operates a share-based payment scheme (the “Scheme”) for the purpose of providing incentives and rewards to eligible participants who contribute to the success of LakeShore Group’s operations. Eligible participants of the Scheme include LakeShore Group’s directors, employees and consultants.

***The 2010 Share Incentive Plan***

On June 21, 2010, LakeShore Group adopted the 2010 Share Incentive Plan (the “Plan”) that has a contractual term of 10 years. The Plan provides for the granting of stock options and other stock-based awards to employees and directors. LakeShore Group’s Board of Directors authorized and reserved for the issuance of up to 272,565 ordinary shares under the Plan for the period from 2010 to 2013, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024.

Starting from January 1, 2014, the maximum number of shares subject to awards that may be granted during any single calendar year is 1.5% of total issued and outstanding shares as of the first business day of that calendar year.

The stock options granted to employees are accounted for as equity awards and measured at their grant date fair values. Options that vest based on service conditions generally will become vested over a three-year period in equal quarterly instalments of 0.08% each on the last day of every quarter that has elapsed until the options are 100% vested.

On January 1, 2015, an annual grant of 12,750 options, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024, which vest based on performance conditions, were granted to various employees. The annual grant was applicable for calendar 2015, 2016, 2017, 2018, 2019 and 2020, respectively. The options become vest in equal quarterly instalments based on performance targets established on January 1st of each calendar year from 2015 to 2020. There are no more grants after December 31, 2020 under the 2010 share incentive plan.

For options granted to LakeShore Group’s senior executives, the grantee can exercise vested options after the commencement date of exercise and before the earlier of: 1) its contractual term (i.e., 10 years after each of its vesting date); or 2) 5 years after the grantee terminates their employment if the vested option has not been exercised.

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For options granted to the remaining employees, the grantee can exercise vested options after the commencement date of exercise and before the earlier of: 1) its contractual term (i.e., 10 years after each of its vesting date); or 2) 12 months after the grantee terminates their employment if the vested option has not been exercised.

For those awards, evaluations are made as of each reporting period to assess the likelihood of performance criteria being met. Share-based payment expenses are then adjusted to reflect the revision of original estimates.

The exercise prices and exercise periods, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024, of the share options outstanding as at the end of each of the Relevant Periods are as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Number of shares options** | |  |  | **Average exercise price per share option** | |  |
|  |  |  | |  |  | **(RMB)** | |  |
| As of March 31, 2023 |  |  | 325,357 |  |  |  | 324.020 |  |
| Granted during the period |  |  | - |  |  |  | - |  |
| Forfeited during the period |  |  | - |  |  |  | - |  |
| Exercised during the period |  |  | - |  |  |  | - |  |
| Expired during the period |  |  | - |  |  |  | - |  |
| As of March 31, 2024 |  |  | 325,357 |  |  |  | 324.020 |  |
| Granted during the period |  |  | - |  |  |  |  |  |
| Forfeited during the period |  |  | - |  |  |  | - |  |
| Exercised during the period |  |  | - |  |  |  | - |  |
| Expired during the period |  |  | - |  |  |  | - |  |
| As of March 31, 2025 |  |  | 325,357 |  |  |  | 324.020 |  |

The exercise prices and exercise periods, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024, of the share options outstanding as at the end of the reporting periods are as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Year Ended 31 March 2025** | |  |  |  | |  |  |  |
| **Number of options** | |  |  | **Exercise price** | |  |  | **Exercise period** |
|  | |  |  | **(RMB)** | |  |  |  |
|  | 153,325 |  |  |  | 139.38 |  |  | 2021-2031 |
|  | 61,337 |  |  |  | 258.524 |  |  | 2021-2026 |
|  | 110,695 |  |  |  | 525.376 |  |  | 2021-2026 |
|  | 325,357 |  |  |  |  |  |  |  |

***Bonus incentive plan***

On January 1, 2015, LakeShore Group launched a bonus incentive program effective for six years from launch date. The bonus incentive program is divided into two six-month periods each calendar year. The bonus incentive program specifies for each monthly tranche in the six-month period an independent performance condition for a stated period of service (i.e., one month). The bonus amount is determined on a monthly basis at month-end by the human resources department based on a reasonably objective performance criteria that serves as a basis for promotion and other compensation decisions. A fixed conversion price is then applied to the employee’s month end bonus to determine the number of ordinary shares to be issued to the employee for each individual month. At the end of each respective six-month period, LakeShore Group finalizes the vested ordinary shares to be issued to the employee.

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Based on the above, the employee does not receive a number of ordinary shares with a FV equal to a predominantly fixed dollar amount on the delivery date. Hence, the ordinary shares granted to employees are accounted for as equity awards. In addition, each monthly tranche should be accounted for as a separate award with its own service inception date, grant-date FV, and respective requisite service period because the employee’s ability to retain (vest in) the award pertaining to the current month is not dependent on service beyond the current month.

***Restricted share units (“RSU”)***

Giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024, on February 1, 2018, LakeShore Group granted 69,250 RSUs to employees under the Plan. The weighted average grant-date FV of restricted shares units granted was $72.4, which was derived from the FV of the underlying ordinary shares. 40,500 out of the 69,250 RSUs were subject to service conditions vesting in six equal semi-annual instalments over three years or eight equal semi-annual instalments over four years, respectively. The remaining 28,750 RSUs had been vested on March 16, 2023 due to the successful closing of the public offering. As of March 31, 2025, all the granted shares are vested, and there were no unrecognized share-based payment expenses related to unvested restricted shares.

Giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024, on July 25, 2018, LakeShore Group granted 27,000 units of RSUs to three independent directors. Starting from the effective date of August 1, 2018, 3,000 RSUs will be awarded to each of the three directors annually, which shall be vested in equal portion of 750 units per three months’ Director services rendered by each director. For each of the new directors, 500 units will be vested for the two-month period starting from August 1, 2018, and the remaining are vested on quarterly basis starting from October 1, 2018 to July 31, 2021. The grant-date FV of the RSU was $18.4, which was derived from the FV of the underlying ordinary shares. As of March 31, 2025, all the granted shares are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

On March 25, 2024, LakeShore Group granted 190,000 units of RSUs to three employees. The RSUs became fully vested upon the date of grant. The grant-date FV of the RSU was $6.5, which was derived from the FV of the underlying ordinary shares. As of March 31, 2025, all the granted shares are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

On March 30, 2024, LakeShore Group granted 20,000 units of RSUs to two employees. The RSUs became fully vested upon the date of grant. The grant-date FV of the RSU was $7.2, which was derived from the FV of the underlying ordinary shares. As of March 31, 2025, all the granted shares are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

On June 1, 2024, LakeShore Group granted 750 units of RSUs to three employees. The RSUs became fully vested upon the date of grant. The grant-date FV of the RSU was $8.4, which was derived from the FV of the underlying ordinary shares. As of March 31, 2025, all the granted shares are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

On June 25, 2024, LakeShore Group granted 37,206 units of RSUs to two employees. The RSUs became fully vested upon the date of grant. The grant-date FV of the RSU was $6.1, which was derived from the FV of the underlying ordinary shares. As of March 31, 2025, all the granted shares are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

On March 20, 2025, LakeShore Group granted 750,000 units of RSUs to one employee. The RSUs became fully vested upon the date of grant. The grant-date FV of the RSU was $2.05, which was derived from the FV of the underlying ordinary shares. As of March 31, 2025, all the granted shares are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

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***The 2020 Share Incentive Plan***

On December 31, 2020, LakeShore Group’s board of directors adopted the 2020 Share Incentive Plan for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with LakeShore Group. Pursuant to such plan, LakeShore Group can grant awards to directors, employees and consultants of LakeShore Group with rights to subscribe for up to 875,000 underlying ordinary shares of LakeShore Biopharma. As of the date of this report, (1) 457,298 shares as RSU incentive shares have been fully vested and issued to the respective directors and employees of LakeShore Group, and (2) 417,702 shares are reserved but not issued, among which, options to subscribe for 347,155 ordinary shares of LakeShore Biopharma are granted to certain senior management and employees of LakeShore Group but not exercised, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024.

***The 2024 Share Incentive Plan***

On May 21, 2024, our board of directors adopted the 2024 Share Incentive Plan for the purpose of granting share-based awards to employees, directors and consultants to incentivize their performance and align their interests with the Company. The 2024 Share Incentive Plan was also approved by our shareholders at an extraordinary general meeting held on May 21, 2024. The maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2024 Share Incentive Plan is initially 571,306 ordinary shares, plus an annual increase on the first day of each fiscal year of the Company during the term of this plan commencing with the fiscal year beginning on April 1, 2025, by (i) an amount equal to 1% of the total number of ordinary shares issued and outstanding on the last day of the immediately preceding fiscal year, or (ii) such lesser number of ordinary shares as may be determined by the Board, provided that the numbers shall be equitably adjusted in the event of any share dividend, subdivision, reclassification, recapitalization, split, reverse split, combination, consolidation or similar transactions. Giving retroactive effect of Share Consolidation in October 2024.

***Amended 2024 Share Incentive Plan***

The 2024 Share Incentive Plan was amended in March 2025, as approved and authorized by our board of directors. To reflect the share consolidation effective on October 1, 2024, and the early utilization of the ordinary shares reserved for issuance under the 2024 Share Plan pursuant to the Evergreen Provision, the 2024 Award Pool under the Amended 2024 Share Incentive Plan was adjusted to 2,479,385 ordinary shares, par value US$0.0002 per share. The remainder of the Amended 2024 Share Incentive Plan remains the same as the 2024 Share Incentive Plan. As of the date of this report, (1) 750,000 shares as RSU incentive shares have been fully vested and issued to the respective directors and employees of LakeShore Group, and (2) 597,617 shares are reserved but not issued or outstanding, among which, options to subscribe for 101,732 ordinary shares of LakeShore Biopharma are granted to certain senior management of LakeShore Group but not exercised, (3) 956,938 shares are not reserved.

Stock-based compensation expense included in LakeShore Group’s consolidated statements of operations and comprehensive loss is as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Research and development |  |  | (997,846 | ) |  |  | - |  |  |  | - |  |  | $ | - |  |
| General and administrative |  |  | 4,502,847 |  |  |  | 9,789,686 |  |  |  | 13,557,214 |  |  |  | 1,888,665 |  |
| **Total stock-based compensation** |  |  | **3,505,001** |  |  |  | **9,789,686** |  |  |  | **13,557,214** |  |  | **$** | **1,888,665** |  |

On August 15, 2022, unanimous written resolution of the board of director of LakeShore Group accepted the notice from a former employee, for the surrender of 14,375 of issued shares with US$0.0002 each in LakeShore Group registered in his name, giving retroactive effect of combination in March 2023 and Share Consolidation in October 2024.

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**NOTE 15—RELATED PARTY TRANSACTIONS AND BALANCES**

The following companies are related parties that had material balances or transactions with LakeShore Group as of and during the fiscal years ended March 31, 2025, 2024 and 2023:

|  |  |  |
| --- | --- | --- |
| **Name of related parties** |  | **Relationship with LakeShore Group** |
| Yisheng Biopharma Holdings Ltd. |  | An entity controlled by Yi Zhang \* |
| Apex Prospect Limited |  | A shareholder of LakeShore Group |
| Beijing Huarui Jingkai Real Estate Co., Ltd |  | An affiliate of Apex Prospect Limited |
| HaiSong Zhiyuan (Beijing) Management Consulting Co., Ltd |  | An entity controlled by Chairman |
| Beijing Yisheng Xingye Technology Co., Ltd., |  | An affiliate of Yisheng Biopharma Holdings Ltd. |
| Yi Zhang\* |  | A shareholder of LakeShore Group |
| Rui Mi |  | Spouse of Yi Zhang |

|  |  |  |
| --- | --- | --- |
|  | \* | Yi Zhang was the shareholder of LakeShore Group. The entity controlled by him was the related parties of LakeShore Group. |

***Transactions with related parties***

LakeShore Group had the following material transactions with related parties during the fiscal years ended March 31, 2025, 2024 and 2023:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Bank loans and other borrowings - current** |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| **Beijing Huarui Jingkai Real Estate Co., Ltd(1)** |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Financing from related parties |  |  | - |  |  |  | - |  |  |  | 311,401,631 |  |  |  | 43,381,576 |  |
| Accrual interest to related parties |  |  | - |  |  |  | - |  |  |  | 7,592,750 |  |  |  | 1,057,751 |  |
| Payment interest to related party |  |  | - |  |  |  | - |  |  |  | 4,139,951 |  |  |  | 576,739 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Apex Prospect Limited(2)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Financing from related parties |  |  | - |  |  |  | - |  |  |  | 3,589,100 |  |  |  | 500,000 |  |
| Accrual interest to related parties |  |  | - |  |  |  | - |  |  |  | 14,457 |  |  |  | 2,014 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Accrued expenses and other liabilities** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **HaiSong Zhiyuan (Beijing) Management Consulting Co., Ltd(3)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  | - |  |
| Related parties provide services to our company |  |  | - |  |  |  | - |  |  |  | 1,815,682 |  |  |  | 252,944 |  |
| Repayment to related party |  |  | - |  |  |  | - |  |  |  | 1,129,968 |  |  |  | 157,417 |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Beijing Yisheng Xingye Technology Co., Ltd.,(4)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Related parties provide services to our company |  |  |  |  |  |  |  |  |  |  | 349,818 |  |  |  | 48,733 |  |
| Repayment to related party |  |  |  |  |  |  |  |  |  |  | 349,818 |  |  |  | 48,733 |  |
| **Beijing Yisheng Xingye Technology Co., Ltd.,(4)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Purchase Property, plant and equipment from related parties |  |  | - |  |  |  | - |  |  |  | 106,195 |  |  |  | 14,794 |  |
| Repayment to related party |  |  | - |  |  |  | - |  |  |  | 106,195 |  |  |  | 14,794 |  |

|  |  |
| --- | --- |
| (1) | In fiscal 2025, LakeShore Group borrowed RMB311.4 million with interest at 5.0% from Beijing Huarui Jingkai Real Estate Co., Ltd, which has accrued interest of RMB7.6 million. Lakeshore Group has paid RMB4.1 million. As of March 31, 2025, the balance of bank loans and other borrowings - current and accrued expenses and other liabilities were RMB311.4 million and RMB3.5 million. |

|  |  |
| --- | --- |
| (2) | In fiscal 2025, LakeShore Group borrowed RMB3.6 million with interest at 5.0% from Apex Prospect Limited, accrued interest RMB0.01 million. As of March 31, 2025, the balance of bank loans and other borrowings - current and accrued expenses and other liabilities were RMB3.6 million and RMB0.01 million. |

|  |  |
| --- | --- |
| (3) | In fiscal 2025, LakeShore Group purchased service RMB1.8 million from HaiSong Zhiyuan (Beijing) Management Consulting Co., Ltd. As of March 31, 2025, the balance of accrued expenses and other liabilities was RMB0.7 million. |

|  |  |
| --- | --- |
| (4) | In fiscal 2025, LakeShore Group purchased service and Property, plant and equipment RMB0.3 million and RMB0.1 million from Beijing Yisheng Xingye Technology Co., Ltd.,. As of March 31, 2025, LakeShore Group repaid it fully. |

|  |  |
| --- | --- |
| (5) | In July 2023, LakeShore Group spent US$20,000 to purchase a vehicle from Rui Mi, spouse of Mr. Yi Zhang, that was subsequently purchased back  by Rui Mi in March 2024. |

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**NOTE 16 – INCOME TAX**

**Cayman Islands.** Under the current laws of the Cayman Islands, LakeShore Biopharma is not subject to tax on income or capital gains. In addition, upon payments of dividends by LakeShore Biopharma to its shareholders, no Cayman Islands withholding tax is imposed.

**Hong Kong.** Under the Hong Kong tax laws, HK Yisheng, as a holding company, is exempted from profit tax on its foreign-sourced income and there are no withholding taxes in Hong Kong on remittance of dividends.

**Singapore.** Singapore LakeShore, a subsidiary incorporated in Singapore, files separate income tax returns in Singapore at the statutory income tax rate of 17%.

**China.** Under the Enterprise Income Tax (“EIT”) Law of the PRC, domestic enterprises and Foreign Investment Enterprises (the “FIE”) are usually subject to a unified 25% EIT rate while preferential tax rates, tax holidays, and even tax exemption may be granted on case-by-case basis. The PRC tax authorities grant preferential tax treatment to High and New Technology Enterprises (“HNTEs”). Under this preferential tax treatment, HNTEs are entitled to an income tax rate of 15%, subject to a requirement that they re-apply for HNTE status every three years. Since Liaoning Yisheng was approved as an HNTE in November 2024, Liaoning Yisheng is entitled to a reduced income tax rate of 15% and is able to enjoy the reduced income tax rate in the next three years. Since Beijing Yisheng was approved as an HNTE in December 2022, Beijing Yisheng is entitled to a reduced income tax rate of 15% and is able to enjoy the reduced income tax rate in the next three years.

**United States.** US Yisheng, a subsidiary incorporated in Maryland, United States is subject to statutory federal corporate income tax at a rate of 21% and state income tax at a rate of 8.25%.

**Philippines.** The subsidiary incorporated in Philippines is subject to income tax at 20%

The provision for income tax consisted deferred tax and current income tax expense.

The following table reconciles the statutory rate to LakeShore Group’s effective tax rate:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |
| PRC statutory income tax rate |  |  | 25.00 | % |  |  | 25.00 | % |  |  | 25.00 | % |
| Effect of different tax rates in different jurisdictions |  |  | (36.00 | )% |  |  | (13.32 | )% |  |  | (41.76 | )% |
| Effect of PRC preferential tax rate |  |  | 8.72 | % |  |  | (3.39 | )% |  |  | 3.99 | % |
| Effect of research and development expenses deduction and others |  |  | 25.50 | % |  |  | 9.97 | % |  |  | 22.25 | % |
| Non-deductible expenses |  |  | - | % |  |  | 0.06 | % |  |  | 18.20 | % |
| Temporary differences\* |  |  | 0.79 | % |  |  | (4.77 | )% |  |  | (4.27 | )% |
| Change in valuation allowance |  |  | (23.23 | )% |  |  | (18.31 | )% |  |  | (24.34 | )% |
| **Effective tax rate** |  |  | **0.78** | **%** |  |  | **(4.76** | **)%** |  |  | **(0.93** | **)%** |

|  |  |
| --- | --- |
| \* | Temporary differences primarily relate to impairment of inventories, property, plant and equipment and other assets, government grants and allowance for expected credit losses. |

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Net deferred tax assets as of March 31, 2025 and 2024, consist of the following key components:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Deferred tax assets:** |  |  |  |  |  |  |  |  |  |  |  |  |
| Write-down of inventories to net realizable value |  |  | 10,223,137 |  |  |  | 4,660,626 |  |  | $ | 649,275 |  |
| Impairment of property, plant and equipment |  |  | 13,542,899 |  |  |  | 15,953,770 |  |  |  | 2,222,532 |  |
| Losses available for offsetting against future taxable profits |  |  | 81,220,037 |  |  |  | 102,196,857 |  |  |  | 14,237,115 |  |
| Others |  |  | 2,951,867 |  |  |  | 8,042,946 |  |  |  | 1,120,468 |  |
| Less: valuation allowance |  |  | (81,220,037 | ) |  |  | (102,196,857 | ) |  |  | (14,237,115 | ) |
| **Total deferred tax assets** |  |  | **26,717,903** |  |  |  | **28,657,342** |  |  |  | **3,992,275** |  |
| **Deferred tax liabilities:** |  |  |  |  |  |  |  |  |  |  | - |  |
| Fair value adjustments arising from historical acquisition of subsidiaries |  |  | (3,083,714 | ) |  |  | (710,842 | ) |  |  | (99,028 | ) |
| **Total deferred tax liabilities** |  |  | **(3,083,714** | **)** |  |  | **(710,842** | **)** |  |  | **(99,028** | **)** |
| **Net deferred tax assets** |  |  | **23,634,189** |  |  |  | **27,946,500** |  |  | **$** | **3,893,247** |  |

In assessing the realizability of the net deferred tax assets, LakeShore Group considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income in the future. Based upon an assessment of the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible or can be utilized. The amount of the deferred tax assets is considered unrealizable because it is more likely than not that LakeShore Group will not generate sufficient future taxable income to utilize this portion of the net operating loss.

***Uncertain tax positions***

There were no uncertain tax positions as of March 31, 2025 and 2024 and management does not anticipate any potential future adjustments which would result in a material change to its tax positions.

**NOTE 17 – DEFERRED GOVERNMENT GRANTS**

Deferred government grants represent funds received from the PRC government for research and development, investment in building or improvement in LakeShore Group’s production facilities. These specific subsidies are recorded as deferred government grants upon receipt and are recognized as government grants when the conditions are met. Other subsidies are recognized as government grants upon receipt as further performance by LakeShore Group is not required. LakeShore Group received specific subsidies that were deferred in the amount of nil and RMB3.6 million in fiscal 2025 and 2024, respectively. In addition, LakeShore Group received RMB0.5 million and RMB15.3 million other subsidies that the government has not set any conditions and are not tied to future trends or performance of LakeShore Group and were recognized as government grants in 2025 and 2024, respectively.

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Deferred government grants included the following:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Government grants for property, plant and equipment** |  |  | |  |  |  | |  |  |  | |  |
| Balance at beginning of the year |  |  | 20,575,012 |  |  |  | 21,735,856 |  |  | $ | 3,028,037 |  |
| Addition |  |  | 3,600,000 |  |  |  | - |  |  |  | - |  |
| Recognized as government grants |  |  | (2,439,156 | ) |  |  | (4,072,433 | ) |  |  | (567,333 | ) |
| **Subtotal** |  |  | **21,735,856** |  |  |  | **17,663,423** |  |  | **$** | **2,460,704** |  |
|  |  |  |  |  |  |  |  |  |  |  | - |  |
| **Government grants for research and development** |  |  |  |  |  |  |  |  |  |  | - |  |
| Balance at beginning of the year |  |  | 5,327,196 |  |  |  | 559,782 |  |  | $ | 77,984 |  |
| Addition |  |  | - |  |  |  | - |  |  |  | - |  |
| Recognized as government grants |  |  | (4,767,414 | ) |  |  | (559,782 | ) |  |  | (77,984 | ) |
| **Subtotal** |  |  | **559,782** |  |  |  | - |  |  | $ | - |  |
| **Total deferred government grants** |  |  | **22,295,638** |  |  |  | **17,663,423** |  |  | **$** | **2,460,704** |  |
|  |  |  |  |  |  |  |  |  |  |  | - |  |
| **Less：current portion** |  |  | **2,015,693** |  |  |  | **1,455,678** |  |  | **$** | **202,792** |  |
|  |  |  |  |  |  |  |  |  |  |  | - |  |
| **Non-current portion** |  |  | **20,279,945** |  |  |  | **16,207,745** |  |  | **$** | **2,257,912** |  |

***Government grants for property, plant and equipment***

LakeShore Group has nine deferred government grants related to property, plant and equipment. RMB4.1 million was amortized from deferred government grants into government grants in fiscal 2025, as compared to RMB2.4 million for the fiscal year ended March 31, 2024. RMB1.5 million will be amortized in fiscal 2026 which was included in the current deferred government grants and RMB16.2 million will be amortized after 2026 which was included in the non-current portion of deferred government grants.

***Government grants for research and development***

LakeShore Group has one deferred government grant related to various research and development projects. RMB0.6 million was amortized from deferred government grants into government grants in fiscal 2025, as compared to RMB4.8 million for the fiscal year ended March 31, 2024.

**NOTE 18 – COMMITMENTS AND CONTINGENCIES**

As of March 31, 2025, LakeShore Group has the following commitments to purchase construction in progress, raw materials and services :

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | |  |
|  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(US$)** | |  |
| Construction in progress |  |  | 5,816,677 |  |  | $ | 810,325 |  |
| Other professional service fees |  |  | 2,900,000 |  |  |  | 404,001 |  |
| Purchase raw materials |  |  | 12,639,493 |  |  |  | 1,760,816 |  |
| Research and development |  |  | 19,200,222 |  |  |  | 2,674,796 |  |
| **Total** |  |  | **40,556,392** |  |  | **$** | **5,649,938** |  |

In 2018, Liaoning Yisheng filed a sales contract dispute with Hebei Defense Biological Products Supply Center. The Supreme People’s Court of Liaoning supported the Liaoning Yisheng’s claim the defendant Hebei Weifang should pay RMB2,465,807 for Liaoning Yisheng vaccine within 20 days after the judgment came into effect. As of the date of this report, LakeShore Group received RMB1,636,755 from Hebei Defense Biological Products Supply Center, and the balance of RMB829,052 may be received in fiscal 2026.

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LakeShore Group was also involved in labor disputes as of March 31, 2025. As the proceedings are in the early stages or the second appeal, there is uncertainty regarding the timing or ultimate resolution of such matters, and therefore, an estimate for the reasonably possible loss or a range of reasonably possible losses cannot be made.

Since December 2023, the Company has been involved in two legal proceedings in the Cayman Islands against Mr. Yi Zhang, the former chairperson of the Board, and his associates.

FSD 400 of 2023

On December 22, 2023, the Grand Court of the Cayman Islands (the “Grand Court”) granted the Company an injunction order against Mr. Zhang, which restrained Mr. Zhang from, among other things, taking any steps to exercise any powers of, or hold himself out to be, chairperson of the Board. That injunction was discharged by the Grand Court on February 6, 2024. On February 16, 2024, the Company obtained another injunction order from the Grand Court which restrained Mr. Zhang and his associates, including Nan Zhang, Yun (Monica) Zhang, Lui Chi Keung and Jing Xian Li from, among other things, holding themselves out to be directors of the Company and from taking any steps to exercise any powers as though they were directors. On April 3, 2024, the Company filed an Amended Statement of Claim with the Grand Court in its proceedings against Mr. Zhang and his associates. The Amended Statement of Claim seeks various forms of declaratory and injunctive relief against the defendants as well as damages. On June 7, 2024, Mr. Zhang filed a Defence with the Grand Court which, among other things, alleges that certain present and former directors of the Company took steps to improperly oust Mr. Zhang from, and to seize control of, the Company and that certain present and former directors of the Company breached their fiduciary duties to the Company (which Mr. Zhang has pleaded will be the subject of separate derivative proceedings) and denies the Company’s entitlement to the relief the Company has claimed in its Amended Statement of Claim. On August 2, 2024, the Company filed and served its Reply by which the Company has, among other things, denied these allegations.

FSD 318 of 2024

In October 2024, Mr. Zhang filed a Writ of Summons and Statement of Claim (“Writ”) with the Grand Court against the Company and 13 of its current or former directors and Apex Prospect Limited (“Apex”), seeking, amongst other things, (i) declarations on the validity of certain actions of the Company’s Board taken since Mr. Zhang was removed as chairperson of the Board in December 2023; (ii) orders setting aside the February 2024 issue by the Company of 95,269,762 shares (which was the number of shares prior to the share consolidation, in consistency with the Writ) to Apex and any allotments of any ordinary shares issued by the Company pursuant to the 2024 Share Incentive Plan approved by the Board in May 2024 or, alternatively, declaring that such share issuance and allotments were done for an improper purpose and in breach of the duties of the directors who approved them; (iii) orders that the Company’s Register of Members be rectified to delete any entries in respect of such share issuance and allotments; (iv) an injunction restraining Apex from exercising any rights attaching to the Company’s shares registered in its name or holding itself out to be a shareholder of the Company; (v) an injunction restraining the Company’s current directors from holding themselves out to be directors of the Company or exercising any powers as directors of the Company; (vi) an injunction restraining the Company and its Board from taking any steps to directly or indirectly allotting any further shares pursuant to the 2024 Share Incentive Plan or taking any actions which may result in the further dilution of Mr. Zhang’s shareholding and/or which would negatively affect the asset value and/or the share price of the Company; and (vii) damages against the director and former director defendants for unlawful means conspiracy against Mr. Zhang.

On October 31, 2024, Mr. Zhang applied to the Grand Court on an ex parte basis for an injunction to restrain the Company from (i) issuing new shares or causing Mr. Zhang’s shareholding to be diluted; and (ii) entering into any transactions or dealings with a value in excess of US$50,000 (other than in the ordinary course of business), each until Mr. Zhang had been given 7 day’s prior notice. On December 13, 2024, the Grand Court refused to hear that application on an ex parte basis. Mr. Zhang’s injunction application was heard on an inter partes basis on January 21 and 22, 2025 and dismissed by the Chief Justice of the Grand Court.

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The Writ of Summons and Statement of Claim in the proceedings commenced by Mr. Zhang were amended on February 7, 2025 and Mr. Zhang discontinued his claims against 6 of the former director defendants on March 21, 2025. The Company and the remaining 7 director defendants filed their Defences to the Amended Statement of Claim on February 24, 2025 and March 17, 2025 respectively. Mr. Zhang filed his Replies to those Defences on March 31, 2025. On April 15, 2025, Mr. Zhang gave notice that he had changed his Cayman Islands attorneys. Mr. Zhang’s new attorneys later gave the Company notice that on or before June 6, 2025 he intended to seek leave to further amend the Amended Writ of Summons and Amended Statement of Claim.

As of the date of this Annual Report, the legal proceedings in the two Cayman Islands are still ongoing and no further judgments have been rendered by the Grand Court. The parties have agreed that they will seek to have Cayman Islands proceedings consolidated and/or heard together going forward.

In May 2024, two entities controlled by Mr. Zhang (each, a “Claimant,” and collectively, the “Claimants”) filed arbitration claims respectively with the Kaifeng Arbitration Commission in China against Liaoning Yisheng. The Claimants sought an aggregate amount of RMB919 million ($128 million) of payment, primarily covering fees for R&D services of RMB198 million ($28 million) and accrued interests, borrowings and other fees of RMB721 million ($101 million) until full payment. The Claimants allege that Liaoning Yisheng owes them fees for research and development services from as early as 2002, and that the parties had entered into debt confirmation and repayment agreements respectively in March 2024, pursuant to which Liaoning Yisheng purportedly agreed to repay the Claimants approximately RMB723 million ($101 million) in the aggregate, including fees for R&D services of RMB198 million ($28 million) and accrued interests, borrowings and other fees of RMB525 million ($73 million) until full payment. Through the two aforementioned arbitration proceedings, the Claimants applied for pre-arbitration preservation of Liaoning Yisheng’s assets, requesting the of funds of up to RMB919 million ($128 million) in Liaoning Yisheng’s bank account (the “Freezing Applications”). Liaoning Yisheng applied to the court assisting the execution of the Freezing Applications to replace the subject assets of the Freezing Applications with its inventory of YSJATM rabies vaccine, certain machinery and equipment and properties, with had an appraisal value of approximately RMB919 milllion ($128 million). In consideration of the potential negative impact from the freezing of the bank accounts on Liaoning Yisheng’s cash flow and business operations, the court granted Liaoning Yisheng’s application.

In May 2024, a Claimant filed arbitration claims with the Kaifeng Arbitration Commission in China against Beijing Yisheng. The Claimant alleged that Beijing Yisheng owed the Claimant certain fees and other amounts since 2021 due to historical reorganization transactions, and that the parties entered into debt confirmation and repayment agreements in March 2024, pursuant to which the Claimant claimed that Beijing Yisheng had agreed to repay the Claimant approximately RMB59 million ($8 million) in the aggregate. The Claimant sought an arbitration award of RMB83 million ($12 million), which included the principal amount and other funds derived therefrom in payment from Beijing Yisheng.

As of the date of this Annual Report, the Kaifeng Arbitration Commission did not issue awards on these three cases.

For the above cases there is uncertainty regarding the timing or ultimate resolution of such matters, and therefore, an estimate for the reasonably possible loss or a range of reasonably possible losses cannot be made.

**NOTE 19 – SEGMENT INFORMATION**

Based on management’s assessment, LakeShore Group has one operating segment, which is the development, production, marketing and sale of biopharmaceutical products. No operating segments were aggregated to form the reportable operating segment.

The CODM regularly reviews the Consolidated Statements of Operations and Comprehensive Loss and a disaggregation of operating expenses, of which the significant expenses are related to testing and clinical trial fees. Testing and clinical trial fees were RMB93,591,766 for the year ended March 31, 2025. Other items which were reviewed include employee benefits, depreciation and amortization, professional service fees, and other expenses. The amount of other items was RMB499,889,555 for the year ended March 31, 2025. The CODM does not regularly review segment assets to make decisions regarding the allocation of resources, and as such the Company has not included assets at this point.

LakeShore Group’s non-current assets are located in the PRC and other countries, such as Singapore and Philippines. The location of these non-current assets can be aggregated to form the reportable geographical segment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| PRC |  |  | 527,009,381 |  |  |  | 484,895,385 |  |  | $ | 67,551,111 |  |
| Other countries/regions |  |  | 17,583,961 |  |  |  | 1,460,716 |  |  | $ | 203,493 |  |

The non-current asset information above is based on the location of the assets and excludes financial instruments and deferred tax assets.

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**NOTE 20 – SUBSEQUENT EVENTS**

LakeShore Group performed an evaluation of events and transactions for potential recognition or disclosure through the date of this report. LakeShore Group is not aware of any material subsequent events other than those disclosed below and elsewhere in the notes to the consolidated financial statements.

From April 14, 2025 to April 28, 2025, LakeShore Group borrowed RMB110.0 million with interest at 5.0% from Zhonghao Financial Leasing (Tianjin) Co., Ltd. The loans are due on March 31, 2026.

On May 12, 2025, Mr. Dave Chenn has resigned as a member of the board of directors, the chairman of the Board, a member of the compensation committee of the Board and a member of the nominating and corporate governance committee of the Board. On the same date, the Board approved the appointment of Mr. Pierson Yue Pan to serve as a member of the Board, the Chairman, a member of the Compensation Committee and a member of the Nominating and Corporate Governance Committee.

On May 16, 2025, LakeShore Group borrowed RMB3.6 million with interest at 5.0% from Apex Prospect Limited. The loans are due on February 17, 2026.

On May 19, 2025, LakeShore Group borrowed RMB100 million with interest at 5.0% from Beijing Huarui Jingkai Real Estate Co., Ltd. The loans are due on May 18, 2026. The loans have not been withdrawn.

On June 3, 2025, the name of the Company’s subsidiary be and hereby is changed from Hu’an Yuanhang Biotechnology (Beijing) Co., Ltd to Hu’an Biotechnology (Beijing) Co., Ltd.

On July 8, 2025, Crystal Peak entered into a Share and Warrant Purchase Agreement with the company, pursuant to which the Company sold 16,987,542 ordinary shares and 16,987,542 detachable warrants in a private placement transaction for a total consideration of US$15 million. Subsequently, on July 9, 2025, these warrants were fully exercised on a cashless basis by Crystal Peak, resulting in the issuance of 4,033,790 ordinary shares.

**NOTE 21 – PARENT COMPANY ONLY CONDENSED FINANCIAL INFORMATION**

Pursuant to the requirements of Rule 12-04(a), 5-04(c) and 4-08(e)(3) of Regulation S-X, the condensed financial information of the parent company shall be filed when the restricted net assets of consolidated subsidiaries exceed 25% of consolidated net assets as of the end of the most recently completed fiscal year. LakeShore Group performed a test on the restricted net assets of consolidated subsidiaries in accordance with such requirement and concluded that it was applicable to LakeShore Group as the restricted net assets of LakeShore Group’s PRC subsidiaries exceeded 25% of the consolidated net assets of LakeShore Group. Therefore, the condensed financial statements of the parent company are included herein.

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**PARENT COMPANY BALANCE SHEETS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **As of March 31,** | | | | | | | | | |  |
|  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **ASSETS** |  |  | |  |  |  | |  |  |  | |  |
| **Current assets** |  |  | |  |  |  | |  |  |  | |  |
| Cash |  |  | 167,227,049 |  |  |  | 3,556,774 |  |  | $ | 495,497 |  |
| Amounts due from related parties |  |  | 1,145,781,243 |  |  |  | 1,057,080,561 |  |  |  | 147,262,623 |  |
| **Total current assets** |  |  | **1,313,008,292** |  |  |  | **1,060,637,335** |  |  |  | **147,758,120** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Non-current assets** |  |  |  |  |  |  |  |  |  |  |  |  |
| Long-term investments |  |  | 165,416,495 |  |  |  | 288,057,858 |  |  |  | 40,129,539 |  |
| Long-term prepaid expense |  |  | 2,341,350 |  |  |  | 1,895,045 |  |  |  | 264,000 |  |
| **Total non-current assets** |  |  | **167,757,845** |  |  |  | **289,952,903** |  |  |  | **40,393,539** |  |
| **Total assets** |  |  | **1,480,766,137** |  |  |  | **1,350,590,238** |  |  | **$** | **188,151,659** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **LIABILITIES AND SHAREHOLDERS’ EQUITY** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Current liabilities** |  |  |  |  |  |  |  |  |  |  |  |  |
| Short-term loans |  |  | - |  |  |  | 3,589,100 |  |  | $ | 500,000 |  |
| Accrued expenses and other liabilities |  |  | 887,485,236 |  |  |  | 840,066,308 |  |  |  | 117,030,218 |  |
| Warrants liability |  |  | 4,548,004 |  |  |  | 3,444,842 |  |  |  | 479,903 |  |
| Amounts due to related parties |  |  | 3,526,595 |  |  |  | 3,735,357 |  |  |  | 520,375 |  |
| **Total current liabilities** |  |  | **895,559,835** |  |  |  | **850,835,607** |  |  |  | **118,530,496** |  |
| **Total liabilities** |  |  | **895,559,835** |  |  |  | **850,835,607** |  |  |  | **118,530,496** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Shareholders’ equity:** |  |  |  |  |  |  |  |  |  |  |  |  |
| Ordinary shares, par value US$0.0002 per share; 250,000,000 shares authorized; 19,022,795 and 20,766,531 shares issued and outstanding as of March 31, 2024 and 2025, respectively \* |  |  | 26,105 |  |  |  | 28,603 |  |  |  | 3,985 |  |
| Additional paid-in capital |  |  | 2,950,862,914 |  |  |  | 2,964,482,986 |  |  |  | 412,984,172 |  |
| Accumulated deficit |  |  | (2,307,502,836 | ) |  |  | (2,407,485,287 | ) |  |  | (335,388,438 | ) |
| Accumulated other comprehensive loss |  |  | (58,179,881 | ) |  |  | (57,271,671 | ) |  |  | (7,978,556 | ) |
| **Total shareholders’ equity** |  |  | **585,206,302** |  |  |  | **499,754,631** |  |  |  | **69,621,163** |  |
| **Total liabilities and shareholders’ equity** |  |  | **1,480,766,137** |  |  |  | **1,350,590,238** |  |  | **$** | **188,151,659** |  |

|  |  |
| --- | --- |
| \* | Gives retroactive effect to the Share Consolidation in October 2024. |

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**PARENT COMPANY STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **（RMB）** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
| **Equity loss of subsidiaries** |  |  | **(138,758,136** | **)** |  |  | **(379,244,652** | **)** |  |  | **(51,605,606** | **)** |  | **$** | **(7,189,213** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Operating expenses:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| General and administrative |  |  | 7,630,726 |  |  |  | 60,553,856 |  |  |  | 50,450,858 |  |  |  | 7,028,344 |  |
| Research and development |  |  | (887,280 | ) |  |  | 33,011 |  |  |  | - |  |  |  | - |  |
| **Total operating expenses** |  |  | **6,743,446** |  |  |  | **60,586,867** |  |  |  | **50,450,858** |  |  |  | **7,028,344** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Loss from operations** |  |  | **(145,501,582** | **)** |  |  | **(439,831,519** | **)** |  |  | **(102,056,464** | **)** |  |  | **(14,217,557** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Other income (expenses):** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Financial expenses |  |  | 1,119 |  |  |  | 1,907,804 |  |  |  | (13,989 | ) |  |  | (1,949 | ) |
| Fair value changes of warrant liability |  |  | 21,358 |  |  |  | 4,458,844 |  |  |  | 1,149,792 |  |  |  | 160,178 |  |
| Other income (expenses) |  |  | - |  |  |  | - |  |  |  | 938,210 |  |  |  | 130,704 |  |
| **Total other income(expense)** |  |  | **22,477** |  |  |  | **6,366,648** |  |  |  | **2,074,013** |  |  |  | **288,933** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Net loss** |  |  | **(145,479,105** | **)** |  |  | **(433,464,871** | **)** |  |  | **(99,982,451** | **)** |  |  | **(13,928,624** | **)** |
| Accretion to redemption value of convertible redeemable preferred shares |  |  | (137,991,697 | ) |  |  | **-** |  |  |  | **-** |  |  |  | **-** |  |
| **Net loss attributable to LakeShore Biopharma** |  |  | **(283,470,802** | **)** |  |  | **(433,464,871** | **)** |  |  | **(99,982,451** | **)** |  |  | **(13,928,624** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Net loss** |  |  | **(145,479,105** | **)** |  |  | **(433,464,871** | **)** |  |  | **(99,982,451** | **)** |  |  | **(13,928,624** | **)** |
| Foreign currency translation adjustment |  |  | (137,500,063 | ) |  |  | (3,767,798 | ) |  |  | 908,210 |  |  |  | 126,523 |  |
| **Total comprehensive loss** |  |  | **(282,979,168** | **)** |  |  | **(437,232,669** | **)** |  |  | **(99,074,241** | **)** |  | **$** | **(13,802,101** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Loss per share\*:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| – Basic and Diluted |  |  | (23.55 | ) |  |  | (40.54 | ) |  |  | (5.22 | ) |  | $ | (0.73 | ) |
| **Weighted average number of ordinary shares outstanding\*:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| – Basic and Diluted |  |  | 6,178,547 |  |  |  | 10,692,312 |  |  |  | 19,158,907 |  |  |  | 19,158,907 |  |

|  |  |
| --- | --- |
| \* | Gives retroactive effect to the Share Consolidation in October 2024. |

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**PARENT COMPANY STATEMENTS OF CASH FLOWS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Years Ended March 31,** | | | | | | | | | | | | | |  |
|  |  | **2023** | |  |  | **2024** | |  |  | **2025** | |  |  | **2025** | |  |
|  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(RMB)** | |  |  | **(US$)** | |  |
|  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Net loss |  |  | (145,479,105 | ) |  |  | (433,464,871 | ) |  |  | (99,982,451 | ) |  | $ | (13,928,624 | ) |
| Equity loss of subsidiaries |  |  | 138,758,136 |  |  |  | 379,244,652 |  |  |  | 51,605,606 |  |  |  | 7,189,213 |  |
| Share-based compensation |  |  | 3,505,001 |  |  |  | 9,789,686 |  |  |  | 13,557,214 |  |  |  | 1,888,665 |  |
| Fair value changes of warrant liability |  |  | (21,358 | ) |  |  | (4,458,844 | ) |  |  | (1,149,792 | ) |  |  | (160,178 | ) |
| Changes in operating assets and liabilities: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Amounts due from related parties |  |  | (520,750,020 | ) |  |  | (105,794,347 | ) |  |  | (33,940,681 | ) |  |  | (4,728,300 | ) |
| Amounts due to related parties |  |  | 260,208 |  |  |  | 110,992 |  |  |  | 208,762 |  |  |  | 29,083 |  |
| Accrued expenses and other liabilities |  |  | 48,377,785 |  |  |  | 33,181,238 |  |  |  | (98,912,548 | ) |  |  | (13,779,575 | ) |
| Prepaid expense |  |  | - |  |  |  | (2,341,350 | ) |  |  | 446,305 |  |  |  | 62,174 |  |
| **Net cash used in operating activities** |  |  | **(475,349,353** | **)** |  |  | **(123,732,844** | **)** |  |  | **(168,167,585** | **)** |  |  | **(23,427,542** | **)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash flows from investing activities: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Payment for long-term investment |  |  | - |  |  |  | (1,523,970 | ) |  |  | **-** |  |  |  | **-** |  |
| **Net cash used in investing activities** |  |  | **-** |  |  |  | **(1,523,970** | **)** |  |  | - |  |  |  | - |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cash flows from financing activities: |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Proceeds from bank loans and other borrowings |  |  |  |  |  |  |  |  |  |  | 3,589,100 |  |  |  | 500,000 |  |
| Proceeds from issuance of ordinary shares |  |  | - |  |  |  | 284,196,000 |  |  |  | - |  |  |  | - |  |
| Proceeds from acquisition |  |  | 252,457,329 |  |  |  | - |  |  |  | - |  |  |  | - |  |
| Offering cost |  |  | (35,884,661 | ) |  |  | - |  |  |  | - |  |  |  | - |  |
| **Net cash provided by financing activities** |  |  | **216,572,668** |  |  |  | **284,196,000** |  |  |  | **3,589,100** |  |  |  | **500,000** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Effect of exchange rate on cash |  |  | 9,210,810 |  |  |  | 5,242,203 |  |  |  | 908,210 |  |  |  | 126,523 |  |
| **Net (decrease) increase in cash** |  |  | **(249,565,875** | **)** |  |  | **164,181,389** |  |  |  | **(163,670,275** | **)** |  |  | **(22,801,019** | **)** |
| **Cash at the beginning of the year** |  |  | **252,611,535** |  |  |  | **3,045,660** |  |  |  | **167,227,049** |  |  |  | **23,296,516** |  |
| **Cash at the end of the year** |  |  | **3,045,660** |  |  |  | **167,227,049** |  |  |  | **3,556,774** |  |  | **$** | **495,497** |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Non-cash transactions:** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Accretion to redemption value of convertible redeemable preferred shares |  |  | (137,991,697 | ) |  |  | - |  |  |  | - |  |  | $ | - |  |
| Equity transaction from warrants |  |  | (8,870,007 | ) |  |  | - |  |  |  | - |  |  | $ | - |  |
| Equity transaction from preferred shares |  |  | 1,636,897,084 |  |  |  | - |  |  |  | - |  |  | $ | - |  |

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