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, 2023

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

YS 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)

Hui Shao, 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$0.00002 per share	**YS**	**Nasdaq Stock Market LLC**
Warrants, each exercisable for one ordinary share	**YSBPW**	**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, 2023, there were 93,058,197 ordinary shares outstanding, par value US$0.00002.

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 by the International Accounting Standards Board ☐	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by 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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INTRODUCTION

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

- "Amended YS Biopharma Articles" means our amended and restated memorandum and articles adopted by special resolution passed on September 23, 2022, which became effective on March 16, 2023;
- "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;
- "Board" means our board of directors;
- "Business Combination" means the transactions contemplated by the Business Combination Agreement which was consummated on March 16, 2023;
- "Business Combination Agreement" means the business combination agreement, dated September 29, 2022 (as may be amended, supplemented, or otherwise modified from time to time), by and among Summit, Merger Sub I, Hudson Biomedical Group and YS Biopharma;
- "Cayman Companies Act" means the Companies Act (as Revised) of the Cayman Islands;
- "CDC(s)" means Chinese Centers for Disease Control and Prevention;
- "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 advices in this Annual Report, excludes Hong Kong, Macau and Taiwan). The term "Chinese" has a correlative meaning for the purpose of this Annual Report;
- "Code" means the Internal Revenue Code of the 1986, as amended;
- "Company," "we," "our," "us," "YS Biopharma," "YS Group" or similar terms means YS Biopharma Co., Ltd. (formerly known as YishengBio Co., Ltd) and/or its subsidiaries, including Merger Sub I, Hudson Biomedical Group, US Yisheng, Singapore Yisheng, HK Yisheng, Liaoning Yisheng, Beijing Yisheng and Philippines Yisheng;
- "Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended;
- "Hudson Biomedical Group" means Hudson Biomedical Group Co., Ltd., an exempted company limited by shares incorporated under the laws of the Cayman Islands and our direct wholly-owned subsidiary;
- "HK Yisheng" means YishengBio (Hong Kong) Holdings Limited, a company incorporated under the laws of Hong Kong with limited liability and our wholly-owned subsidiary;
- "KOL(s)" means key opinion leaders;
- "Liaoning Yisheng" means Liaoning Yisheng Biopharma Co., Ltd., a company with limited liability under the laws of the PRC with limited liability and our wholly-owned subsidiary;
- "Merger Sub I" means Oceanview Bioscience Acquisition Co., Ltd., an exempted company limited by shares incorporated under the laws of the Cayman Islands, which was struck off as part of the First Merger;
- "Nasdaq" means the Nasdaq Stock Market;
- "Ordinary Share" means our ordinary shares, par value $0.00002 per share, the rights, preferences, privileges and restrictions of which are set out in the Amended YS Biopharma Articles.
- "PCAOB" means the Public Company Accounting Oversight Board;
- "Philippines Yisheng" means YS BIOPHARMA (PHILIPPINES) INC., a company incorporated under the laws of the Philippines with limited liability and our wholly-owned subsidiary;

- "PFIC" means a "passive foreign investment company" for U.S. federal income tax purposes.
- "PRC" means the People's Republic of China;
- "Sarbanes-Oxley Act" means the Sarbanes-Oxley Act of 2002, as amended;
- "SEC" means the U.S. Securities and Exchange Commission;
- "Securities Act" means the Securities Act of 1933, as amended;
- "Singapore Yisheng" means Yisheng Biopharma (Singapore) Pte. Ltd., (formerly known as Newbiomed Pika Pte. Ltd.), a company incorporated under the laws of Singapore and our wholly-owned subsidiary;
- "Summit" means Summit Healthcare Acquisition Corp., an exempted company limited by shares incorporated under the laws of the Cayman Islands;
- "U.S. dollars," "US$" or "$" means United States dollars, the legal currency of the United States;
- "U.S. GAAP" means accounting principles generally accepted in the United States as in effect from time to time;
- "US Yisheng" means Yisheng US Biopharma Inc., a company incorporated under the laws of U.S. and our wholly-owned subsidiary;
- "Warrant" means warrant to purchase Ordinary Share, with each whole warrant entitling the holder to purchase one Ordinary Share; and
- "YS Biopharma Share Consolidation" means the consolidation of every four pre-consolidation Ordinary Shares and options of YS Biopharma into one Ordinary Share and one option of YS Biopharma, respectively, subject to rounding up to the nearest whole number of shares; and

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 RMB6.8717 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, 2023. 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.

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:

- the regulatory environment and changes in laws, regulations or policies in the jurisdictions in which we operate;
- our ability to successfully compete in highly competitive industries and markets;
- our ability to continue to adjust our offerings to meet market demand, attract customers to choose our products and services and grow our ecosystem;
- political instability in the jurisdictions in which we operate;
- the overall economic environment and general market and economic conditions in the jurisdictions in which we operate;
- our ability to execute our strategies, manage growth and maintain our corporate culture as we grow;
- our anticipated investments in new products, services, collaboration arrangements, technologies and strategic acquisitions, and the effect of these investments on our results of operations;
- our ability to develop and protect intellectual property;
- changes in the need for capital and the availability of financing and capital to fund these needs;
- anticipated technology trends and developments and our ability to address those trends and developments with our products and services;
- the safety, affordability, convenience and breadth of our products and services;

- 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;

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

- exchange rate fluctuations;

- changes in interest rates or rates of inflation;

- legal, regulatory and other proceedings; and

- our ability to maintain the listing of our securities on Nasdaq; and the results of future financing efforts.

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.

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

Holding Company Structure

We are a Cayman Islands holding company that conducts our operations in multiple countries, including China, Singapore and the Philippines through our subsidiaries, including Beijing Yisheng, Liaoning Yisheng, Singapore Yisheng, US Yisheng and Philippines Yisheng. 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.

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 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."

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. While our auditor, Wei, Wei & Co., LLP, is headquartered in the United States and not subject to such determinations, there is no guarantee that the audit work carried out by Wei, Wei & Co., LLP with collaboration of its China-based offices can be inspected or investigated completely by the PCAOB without such approval. 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 continues to demand complete access in mainland China and Hong Kong moving forward and is making plans to resume regular inspections in early 2023 and beyond, as well as to continue pursuing 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 2023 or beyond, 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 HFCAA if the PCAOB is unable to inspect auditors with presence in China in 2023 or beyond, and the delisting of our securities, or the threat of their being delisted, may materially and adversely affect the value of your investment."

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 made distributions to 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, 2021, 2022 and 2023, we did not transfer any cash proceeds to any of our PRC subsidiaries except for the cash transfers within our Group in connection with the paid-in capital in our PRC subsidiaries. $59,900,000, $45,099,071 and nil of the registered capital was paid up by HK Yisheng to Liaoning Yisheng during the fiscal years ended March 31, 2021, 2022 and 2023, respectively. 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 will pay dividends to our 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.”

Emerging Growth Company

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), and, as such, may elect to comply with certain reduced public company reporting requirements in future reports.

Foreign Private Issuer

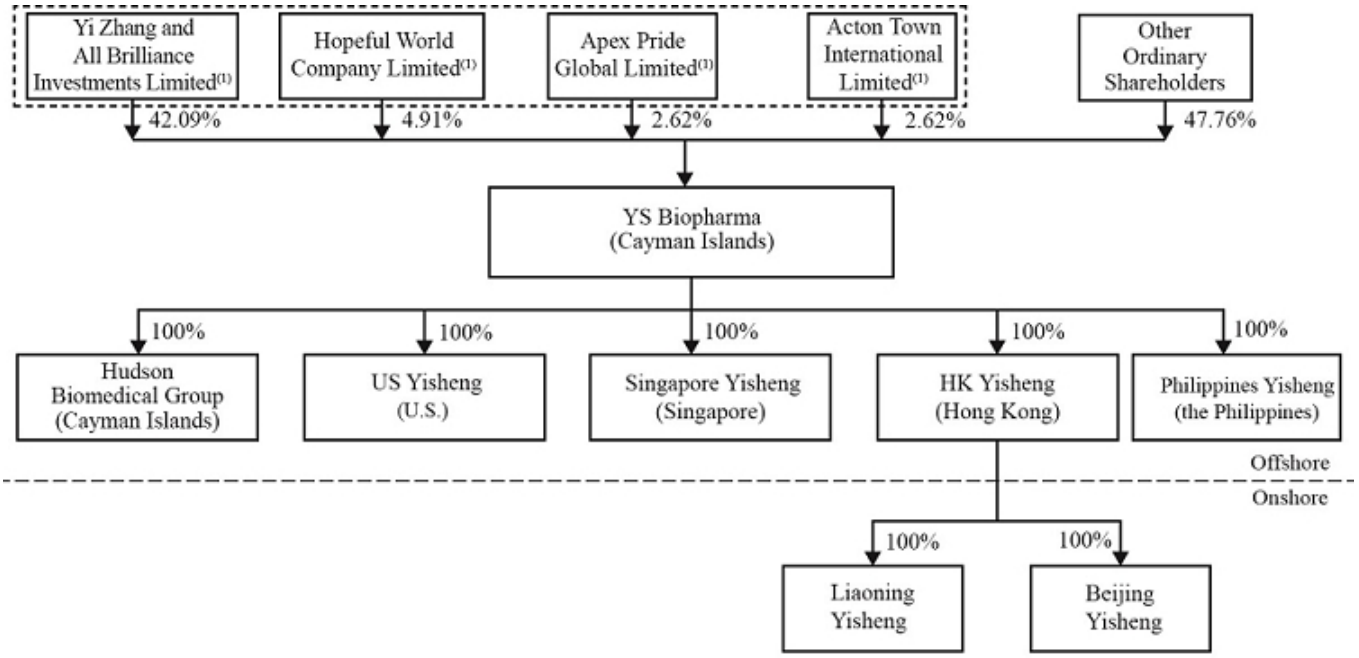
We are also a “foreign private issuer” as defined in the Exchange Act and is exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions under Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the U.S. Securities and Exchange Commission as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

Controlled Company

We are a “controlled company” as defined under the Nasdaq corporate governance rules, because Mr. Yi Zhang, our Founder and Chairman of our Board of Directors, beneficially controls over 50% of the total voting power of all issued and outstanding Ordinary Shares through the acting-in-concert arrangement under a certain concert party agreement. See “Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert Party Agreement” for details. As a result, Mr. Yi Zhang has the ability to exercise significant influence over matters requiring approval by shareholders, such as decisions regarding election of directors and other significant corporate actions. We do not currently plan to utilize the exemptions available for controlled companies, but instead, we intend to rely on the exemption available for foreign private issuers to follow our home country governance practices. As a result, you will not have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements. For details, see “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 are permitted to adopt 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 opt to rely on such exemptions in the future, such decision might afford less protection to holders of our ordinary shares” and “Item 3. Key Information—D. Risk Factors—Risks Related to Ownership of the Ordinary Shares—We are a “controlled company” within the meaning of the Nasdaq Stock Market listing rules and, as a result, may rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.”

Corporate Structure

The following diagram illustrates our corporate structure as of the date of this Annual Report.



(1) (i) Mr. Yi Zhang and the entities he controls, including An Diang Group Holdings Limited, YXRT Company Limited and All Brilliance Investments Limited; (ii) Ms. Rui Mi and the entities controlled by Ms. Rui Mi, including Honeydrew Flower Field Ltd., ZM Home Limited and Hopeful World Company Limited; (iii) Ms. Xu Zhang and the entities controlled by Ms. Xu Zhang, including Apex Pride Global Limited, Prosperous Sunrise Company Limited and Much Galaxy Company Limited; and (iv) Ms. Nan Zhang and the entities controlled by Ms. Nan Zhang, including Spring Nanmu Islands Ltd., NNZF Company Limited and Acton Town International Limited (the "Concert Parties") entered into a concert party agreement dated March 3, 2021 (the "Concert Party Agreement"), pursuant to which, the concert parties agree and acknowledge that they have voted since commencement of our business, and will continue to vote, themselves or through any entity directly or indirectly controlled by them that own our equity interest, unanimously for any resolutions proposed at our board meetings and/or shareholders meeting, where applicable. According to the Concert Party Agreement, if the Concert Parties are unable to reach unanimous consensus, Yi Zhang is entitled to determine how to vote for and on behalf of himself and the Concert Parties. The Concert Agreement remains effective unless otherwise terminated by mutual consent of the Concert Parties.

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary Risk Factors

Risks Related to Our Business and Products

- 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 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.

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

- 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 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.

- 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.

- 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.

- 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.

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

- 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.

- 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.

- 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.

- 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.

- 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:

- 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. While our auditor, Wei, Wei & Co., LLP, is headquartered in the United States and not subject to such determinations, there is no guarantee that the audit work by Wei, Wei & Co., LLP in collaboration of its China-based offices can be inspected or investigated completely by the PCAOB without such approval. 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 continues to demand complete access in mainland China and Hong Kong moving forward and is making plans to resume regular inspections in early 2023 and beyond, as well as to continue pursuing 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 2023 or beyond, 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."

- 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.

- 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."

- 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."

Risks Related to Ownership of the Ordinary Shares

- The price of the Ordinary Shares may be volatile, and the value of the Ordinary Shares may continue to decline.
- We are an emerging growth company and may take advantage of certain reduced reporting requirements.
- 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.
- If we fail to remediate our material weakness 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.
- 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 YSJA™ 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, 2021, 2022 and 2023, revenues from sales of rabies vaccine accounted for approximately 100% of our total revenues. Our ability to continuously commercialize YSJA™ 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 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.

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 YSJA™ 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 YSJA™ 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.

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:

- the competing product may be, or may be perceived to be, more effective, safer or otherwise superior in quality or brand recognition;
- the competing product was introduced to the market earlier or gained wide market acceptance;

- the competing product incorporates more recent technological innovations or research findings;
- the competitor may have greater access to certain raw materials;
- the competitor may have more efficient manufacturing processes, greater manufacturing capacity or lower manufacturing costs;
- 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;
- the competitor may have stronger relationships or a more established history with regulatory bodies, and may obtain regulatory approval for their products more rapidly;
- the competitor may have more aggressive marketing strategies, greater marketing capabilities or pricing flexibility;
- the competing product might be protected by robust patent protections or enjoy market exclusivity;
- the competitor might have more extensive distribution networks or strategic partnerships; or
- 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.

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 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. 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:

- development, safety and efficacy, availability and affordability of alternative therapeutics;
- perception, recognition and acceptance of vaccines by end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry;
- technological and scientific advancements, as well as manufacturing, storage and transportation techniques related to vaccines;
- general awareness on public health;

- changes in demographic composition and structure;
- changes in the regulatory environment, government policy and utilization of resources on public health matters;
- changes in insurance coverage of insurance companies and government programs;
- the occurrence of global health crises; and
- the general economic condition in China and globally.

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:

- manmade or naturally occurring errors and imprecision in the manufacturing, storage, testing, delivery and other procedures;
- technical or mechanical malfunctions in the manufacturing, storage, testing, delivery and other procedures;

- human error or malfeasance by our quality control, quality assurance, manufacturing, experiment and other personnel, as well as other responsible personnel of third parties;
- tampering or interference by external entities or third parties;
- use of outdated or poorly maintained equipment or technology;
- insufficient or ineffective quality control systems;
- non-compliance or negligence of regulatory guidelines by third-party collaborators, suppliers or vendors;
- exposure to suboptimal manufacturing, storage, testing and delivery conditions or environment; and
- quality issues with the raw materials and consumables we purchase or produce.

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 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.

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

- we could be sued and held liable for adverse events to subjects in clinical trials or patients and the relevant compensation, regardless whether a causal relationship can be proven;
- we may suspend commercialization and marketing of the product;
- regulatory authorities may withdraw approvals of the product;
- we are subject to regulatory seizure of our products;
- regulatory authorities may require additional warnings on the label;
- 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;
- we may be required to or propose by ourselves to conduct post-market studies; and
- 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 PIKA rabies vaccine, PIKA recombinant COVID-19 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:

- successfully enrolling and/or completing preclinical studies and clinical trials, as well as other studies required to obtain regulatory approval;
- obtaining regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or product registrations, manufacturing and commercialization;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- 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;

- relying on third parties to manage and conduct high-quality clinical trials safely and efficiently;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring that we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- commercializing our product candidates;
- obtaining reimbursement from third-party payers for product candidates;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- competing with other products and product candidates in the market;
- successfully enforcing and defending intellectual property rights and claims; and
- 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.

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:

- 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;
- regulatory authorities may disagree with or change their position on the acceptability of our trial designs or clinical endpoints;
- clinical trials may produce negative or inconclusive results, which could cause us to conduct additional clinical trials or abandon product development programs;

- 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;

- 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;

- 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;

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

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

- 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;

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

- 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;

- 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;

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

- 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

- 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.

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:

- development, safety and efficacy, availability and affordability of alternative therapeutics;
- perception, recognition and acceptance of vaccines by end-users, CDCs, KOLs and others related to the vaccine or disease prevention industry;
- technological and scientific advancements, as well as manufacturing, storage and transportation techniques related to vaccines;
- general awareness on public health;
- changes in demographic composition and structure;
- changes in regulatory environment, government policy and utilization of resources on public health matters;
- changes in insurance coverage of insurance companies and government programs;
- the occurrence of global health crises;
- the general economic condition in China and globally.

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.

Restrictions imposed by our outstanding indebtedness and any future indebtedness may limit our ability to operate our business and to finance our future operations or capital needs.

In March 2022, we completed a $40 million royalty-based 4.5-year long-term debt transaction with R-Bridge Investment Holdings Pte. Ltd. The terms of the loan facility limit our ability to, among other things, incur additional indebtedness, incur liens on our assets, engage in consolidations, mergers, liquidations, dissolutions, sell or otherwise dispose of our assets, acquire other businesses, make loans, capital contributions, or other investments, or enter into any other transactions outside of the ordinary course of business. In addition, we are obliged to pay royalties based upon our annual Net Sales (as defined in the royalty deed dated March 16, 2022 entered into between HK Yisheng and R-Bridge Healthcare Fund, LP) by multiplying the applicable royalty rate by the corresponding amount incremental Net Sales for that financial year. The terms of our loan facilities and royalty obligations restrict our current and future operations and could adversely affect our ability to finance our future operations or capital needs or take advantage of financing opportunities, mergers, acquisitions, investments, and other corporate opportunities that may be beneficial to our business. In addition, complying with these covenants may make it more difficult for us to successfully execute our business strategy and compete against companies which are not subject to such restrictions.

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.

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 our 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.

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 may experience delays in payments from these CDCs due to bureaucratic processes, changes in governmental policies or budget constraints, which could impact 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. 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.

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.

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:

- decreased demand for we marketed product and product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative media attention and reputational damage;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- hindered relationships with strategic partners, third party service providers, or regulatory authorities;
- loss of existing or potential collaborations or contracts;
- a negative impact on our ability to recruit and retain key personnel;
- increased insurance premiums or inability to obtain insurance coverage;

- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- inability to commercialize any product candidates that we may develop;
- initiation of scrutiny investigations by regulators and authorities, leading to more stringent regulatory requirements;
- a diversion of management's time and our resources; and
- 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.

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 May 28, 2019, which became effective on July 1, 2019, in case foreign organizations and institutions established or actually controlled by foreign organizations or individuals intend to use PRC human genetic resources to carry out scientific research activities, such activities shall abide by PRC laws and regulations and be carried out in cooperation with scientific research institutions, higher education institutions, medical institutions and enterprises in China. Where clinical institutions, to obtain marketing licenses of relevant drugs and medical devices in China, make use of PRC human genetic resources to carry out international cooperation in clinical trials in clinical institutions not involving the exit of PRC human genetic resource materials, approval is not needed. Instead, the cooperating parties shall, before conducting clinical trials, submit the types, quantities and uses of the human genetic resources involved to the administrative department of science and technology for filing. The Implementation Measures of Administrative Regulations of the PRC on Human Genetic Resources, which further specify the definition of foreign entities, filing of international cooperation and relevant administrative penalties, was promulgated by the Ministry of Science and Technology on May 26, 2023, and came into effect on July 1, 2023. 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.

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. Drafts of some department regulations for such protection have been published, including the Data Security Management Measures (Draft for Comments) published in May 2019, which may, upon issuance, require security review before transferring human health-related data out of China. 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.

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 multiple manufacturing plants in Shenyang 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 and Singapore 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.

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:

- monetary penalties;
- product recalls or seizure;
- injunctions;
- refusal of regulatory agencies to review pending manufacturing approval applications or supplements to approval applications;
- total or partial suspension of production;
- confiscation of products;
- withdrawals, revocation or non-renewal of approvals, license or permits previously issued; and
- 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:

- injury or death of patients;
- severe decrease in the demand for, and sales of, the relevant products;
- recall or withdrawal of the relevant products;
- revocation of regulatory approvals for the relevant products or the relevant production facilities;
- damage to the brand name of our marketed product and our reputation;
- stricter and more frequent regulatory inspections of our manufacturing facilities and products;
- inability to participate in the centralized tender process;
- delays or disruptions in our ability to develop new products or expand into new markets;
- exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties; and
- 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 maintain or renew relevant qualifications; (4) engaging in non-compliant conducts, especially in those areas out of our direct supervision; (5) failure to protect our proprietary information and intellectual properties despite of the contractual obligation; and (6) 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.

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.

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. 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.

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 RMB191.8 million, RMB106.0 million and RMB145.5 million ($21.2 million) for the fiscal years ended March 31, 2021, 2022 and 2023, 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:

- experiences the sales growth of YSJA™ rabies vaccine;
- continues to advance the clinical trials and preclinical studies of our current pipelines;
- initiates preclinical, clinical or other studies for new product candidates;

- manufactures materials for clinical trials and for commercial sale;
- seeks regulatory approvals for our product candidates that successfully complete clinical trials;
- 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;
- acquires or in-licenses other product candidates and technologies;
- maintains, protects and expands our intellectual property portfolio and compliance system;
- attracts and retains skilled personnel; and
- 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.

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, 2023, we primarily funded our operations through investments from investors, bank borrowings, proceeds from Business Combination and cash from sales of our marketed rabies vaccines and new product launches for the next 5 years. 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:

- 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;
- the commercialization and sales of our product candidates at discovery and clinical stage;
- the progress, results and costs of the clinical, preclinical and other studies of our product candidates;
- the timing, receipt, and amount of sales of, or royalties or milestone payments on, our future products, if any;
- discovery of new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- 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
- 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.

Our ability to obtain additional financing from exercise of 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 one Ordinary Share at $11.50. Therefore, if and when the trading price of the Ordinary Shares is less than $11.50 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—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, 2023 and may continue to experience such cash outflow for the foreseeable future.

We had net cash used in operating activities of RMB246.6 million, RMB173.5 million and RMB182.5 million ($26.6 million) for the fiscal years ended March 31, 2021, 2022 and 2023, respectively, and we may not be able to achieve or sustain 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 in 2023, we may continue to have net liabilities in the foreseeable future and be exposed to liquidity risk.

We had net liabilities (or total deficit) of RMB508.9 million and RMB699.0 million as of March 31, 2021 and 2022, respectively. The increase in our total deficit was primarily attributable to the increase in the fair value of our convertible redeemable preferred shares and convertible notes which we recognized as liabilities.

While we achieved a positive shift in our financial position with an equity balance of RMB728.5 million ($106 million) as of March 31, 2023, 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.

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

As of March 31, 2021, 2022 and 2023, we had intangible assets of RMB83.8 million, RMB80.7 million and RMB78.1 million ($11.4 million), respectively, which primarily consisted of patents relating to our PIKA adjuvant technology and other licenses, certificates and intellectual properties relating to our business operations. 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, 2021, 2022 and 2023, we had trade receivables of RMB214.5 million, RMB308.6 million and RMB463.1 million ($67.4 million), respectively. As of March 31, 2023, our trade receivables primarily represented amounts due from county-level CDCs attributable to the sales of YSJA™ rabies vaccines. As a result, we may be exposed to credit risks. We recorded allowance for impairment of trade receivables of RMB8.5 million, RMB13.6 million and RMB24.4 million ($3.5 million) as of March 31, 2021, 2022 and 2023, respectively.

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 adopted the 2020 Share Incentive Plan and granted certain awards to our directors, employees and consultants. We believe the grant of share-based compensation is important to our ability to attract, retain and motivate our management team and qualified employees. Upon consummation of the Business Combination, we have assumed such share incentive plan and the outstanding awards granted by us then. As of the date of this Annual Report, there are 6,656,582 Ordinary Shares reserved for our share incentive plans.

We recorded share-based payment expenses of RMB76.8 million, RMB7.8 million and RMB3.5 million ($0.5 million) for the fiscal years ended March 31, 2021, 2022 and 2023, 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.

Restrictions imposed by our outstanding indebtedness and any future indebtedness may limit our ability to operate our business and to finance our future operations or capital needs.

In March 2022, we completed a $40 million royalty-based 4.5-year long-term debt transaction with R-Bridge Investment Holdings Pte. Ltd. The terms of the loan facility limit our ability to, among other things, incur additional indebtedness, incur liens on our assets, engage in consolidations, mergers, liquidations, dissolutions, sell or otherwise dispose of our assets, acquire other businesses, make loans, capital contributions, or other investments, or enter into any other transactions outside of the ordinary course of business. In addition, we are obliged to pay shall pay royalties based upon our annual Net Sales (as defined in the royalty deed dated March 16, 2022 entered into between HK Yisheng and R-Bridge Healthcare Fund, LP) by multiplying the applicable royalty rate by the corresponding amount incremental Net Sales for that financial year. The terms of our loan facilities and royalty obligations restrict our current and future operations and could adversely affect our ability to finance our future operations or capital needs or take advantage of financing opportunities, mergers, acquisitions, investments, and other corporate opportunities that may be beneficial to our business. In addition, complying with these covenants may make it more difficult for us to successfully execute our business strategy and compete against companies which are not subject to such restrictions.

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."

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, 2023 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. In addition, Chinese regulators set forth a framework for integrating data exclusivity into the Chinese regulatory regime, but no specific regulations were issued. 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. However, it is not entirely clear what procedures must be followed in order to apply for such extension.

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.

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.

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 30 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.

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.

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:

- lose the rights to manufacture, market or sell certain products;
- experience significant delays in the development or commercialization of product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all;
- need to allocate resources for damage control and remediation which would otherwise have been used for commercialization and business activities;
- initiate legal proceedings against our former partners or have such proceedings initiated against us and
- 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.

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:

- 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;
- 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;
- 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;

- 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;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may 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.

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, the United States, 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 are still at early stage 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:

- localization of our products, including adaptation to local practices and regulatory requirements;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- 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;
- changes in the political and cultural climate or economic condition of a specific country or region;
- lack of familiarity with and unexpected changes in applicable foreign regulatory regimes;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- more extended accounts receivable payment cycles and difficulties in collecting payments;
- difficulties in managing and staffing overseas operations;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- workforce uncertainty and labor unrest;
- 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;
- potentially adverse tax consequences, including the complexities of transfer pricing, foreign value-added tax systems and restrictions on the repatriation of earnings;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- dependence on certain third parties, such as local distributors or joint venture partners, with whom we do not have extensive experience;
- potential third-party patent rights infringement and difficulties to enforce intellectual property rights;
- increased financial accounting and reporting burdens and complexities;
- political, social, and economic instability abroad, including war and terrorism, and security concerns in general such as natural disasters; and
- 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 approval, filing, permit or license before we commence the construction under PRC laws and regulations. As of the date of this Annual Report, we have commenced construction or improvement of certain facilities and our use before obtaining the relevant approvals, permits and filings or going through the requisite procedures regarding, among others, construction, environmental protection, fire prevention and safety conditions. We cannot assure you that we have obtained and fully complied with, or will be able to obtain and fully comply with such approval, filing, permit, license or other requisite procedures. If we are found to be non-compliant with, relevant laws and regulation, 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.

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 social insurances and housing reserve fund contributions 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.

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 expertise and experience of Mr. Yi Zhang, our founder and chairman in our business operations, and on his personal relationships with the regulatory authorities, our customers, suppliers and employees. We also rely on the healthcare industry-related experience and professional knowledge of our other 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.

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 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, 2021, 2022 and 2023, we had RMB83.8 million, RMB80.7 million and RMB78.1 million ($11.4 million) in intangible assets, 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.

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 RMB246.6 million, RMB173.5 million and RMB182.5 million ($26.6 million) for the fiscal year ended March 31, 2021, 2022 and 2023, respectively. We expect our expenses to increase in connection with our ongoing activities, particularly as we launch and 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:

- our future financial condition, results of operations, outcomes of ongoing research and development, and cash flows;
- the condition of US and other capital markets in which we may seek to raise funds;

- investors' perception of, and demand for, securities of biopharmaceutical companies;
- economic, political and other conditions or crises in China and elsewhere;
- regulatory changes;
- availability of government grants and incentives; and
- 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.

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.

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 YSJA™ 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.

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 November 14, 2021, the CAC released the Regulations for the Administration of Network Data Security (Draft for Comment) (the "Draft Administrative Regulation"). Under the Draft Administrative Regulation, (1) data processors, i.e., individuals and organizations who can decide on the purpose and method of their data processing activities at their own discretion, that process personal information of more than one million individuals shall apply for cybersecurity review before listing in a foreign country; (2) foreign-listed data processors shall carry out annual data security evaluation and submit the evaluation report to the municipal cyberspace administration authority; and (3) where the data processor undergoes merger, reorganization and subdivision that involves important data and personal information of more than one million individuals, the recipient of the data shall report the transaction to the in-charge authority at the municipal level. The public comment period for the Draft Administrative Regulation ended on December 13, 2021, and the Draft Administrative Regulation has not come into effect as of the date of this Annual Report. 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, reporting or other permission requirements by the CAC under the applicable PRC cybersecurity laws and regulations with respect to the offering of our securities for the Business Combination or 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 Combination and 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 Draft Administrative Regulations 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 the Business Combination or 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.

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 2023 and beyond, 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 contained in this Annual Report, have been audited by WWC, an independent registered public accounting firm that is headquartered in the United States. WWC 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 WWC 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 in this Annual Report may not be inspected by the PCAOB, since the audit work was carried out by WWC with the collaboration of their China-based offices and the PCAOB has not obtained such requisite approval. 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. While our auditor, Wei, Wei & Co., LLP, is headquartered in the United States and not subject to such determinations, there is no guarantee that the audit work carried out by Wei, Wei & Co., LLP in collaboration of its China-based offices can be inspected or investigated completely by the PCAOB without such approval. 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 continues to demand complete access in mainland China and Hong Kong moving forward and is making plans to resume regular inspections in early 2023 and beyond, as well as to continue pursuing 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.

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 2023 and beyond, 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 the Nasdaq Stock Market 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 the Nasdaq Stock Market 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 YSJA™ 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.

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. China has responded by imposing, and proposing to impose additional, new, or higher tariffs on certain products imported from the United States. Following mutual retaliatory actions for months, on January 15, 2020, the United States and China entered into the Economic and Trade Agreement Between the United States of America and the PRC as a phase one trade deal, effective on February 14, 2020. Although the direct impact of the current international trade tension, and any escalation of such tension, on the holographic technology industry in China is uncertain, the negative impact on general, economic, political and social conditions may adversely impact 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.

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 owner 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 the 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.

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 corporate structure following the Business Combination, YS Biopharma, which is our Cayman Islands holding company primarily relies on dividend payments from our PRC subsidiaries to fund any cash and financing requirements we may have. Under the existing exchange restrictions, without prior approval of the SAFE, cash generated from the operations of PRC subsidiaries in China may be used to pay dividends to YS Biopharma. However, 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, YS Biopharma needs 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.

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, all of our PRC subsidiaries have negative or very limited net assets, which prevents them from providing loans to them using the Net Assets Limit. 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.

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 their officers and directors outside the U.S. will be limited and addition 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 a minority of our directors reside outside the United States, and a substantial portion of the assets of those persons are located outside of the United States. For example, certain our directors and officers reside in mainland China and one independent director resides in Hong Kong. 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.

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 an exempted company limited by shares incorporated under the laws of the Cayman Islands, and we will continue to conduct a majority of our operations through our subsidiaries, namely Philippines Yisheng, Singapore Yisheng, Liaoning Yisheng and Beijing Yisheng, outside the United States. Substantially all of our assets are located outside of the United States. A majority of our officers and a minority of our directors reside outside the United States and a substantial portion of the assets of those persons are located outside of the United States, including, among others, certain of our directors and officers reside in mainland China and one of our independent directors resides in Hong Kong. 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 Amended YS Biopharma 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 the 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 Amended YS Biopharma 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.

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. We engaged third-party human resources agencies to pay social insurance and housing funds for certain employees for their actual needs to participate in local social insurance and housing fund schemes in their place of residency where we did not have subsidiaries. The contributions of social insurance premium and housing provident funds made through third-party accounts may not be recognized as contributions made by us, and as a result, we may be required by competent authorities to pay the outstanding amount and could be subject to late payment fines and other penalties or enforcement application made to the court. See "—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 provident fund for our 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 deemed to be a PRC tax resident under the EIT Law following the consummation of the Business Combination, and as a result, their global income could be subject to PRC withholding tax and enterprise income tax.

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 partially amended by Circular 9 promulgated in January 2014, 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.

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 SSAT 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.

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 the ADSs 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 the ADSs 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.

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, we or certain of our officers and directors outside the U.S. will be limited and addition 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.

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

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:

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- changes in the pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products and industry;
- announcements by us or our competitors of significant business developments, acquisitions, strategic partnerships or new offerings;
- sales of the Ordinary Shares by us or our shareholders as well as the exercise of options;
- significant product recalls, regulatory investigations, disruptions to or other incidents involving our products;
- our involvement in litigation;
- conditions or advancements, breakthroughs, developments affecting the vaccine industries;
- future sales of the Ordinary Shares by us or our shareholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- the trading volume of the Ordinary Shares;
- changes in the anticipated future size and growth rate of our markets;
- changes in market sentiment towards the healthcare or biopharmaceutical sector, or shifts in investment trends;

- 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;

- changes in general economic, political, regulatory, market conditions; and

- 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.

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.

Following the Business Combination, 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 the Nasdaq Stock Market LLC 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 the Nasdaq Stock Market LLC 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.

Provisions in the Amended YS Biopharma 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 Amended YS Biopharma 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 and/or YS Biopharma Preference 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.

- The Amended YS Biopharma 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.

- The Amended YS Biopharma 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.

- Under the Amended YS Biopharma 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 Amended YS Biopharma 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 Summit 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 Summit 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.

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. 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 JOBS Act, 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.

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

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

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current re-ports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- 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 are permitted to adopt 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 opt to rely on such exemptions in the future, such decision might afford less protection to holders of our ordinary shares.

As a Cayman Islands exempted company that is listed on the Nasdaq Stock Market LLC, we are subject to the Nasdaq listing standards. 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. The corporate governance practice in our home country, the Cayman Islands, does not require a majority of our board of directors to consist of independent directors or the implementation of a nominating and corporate governance committee. Since a majority of our board of directors would not consist of independent directors if we relied on the foreign private issuer exemption, fewer board members would be exercising independent judgment and the level of board oversight on the management of we might decrease as a result. In addition, we could opt to follow Cayman Islands law instead of the Nasdaq requirements that mandate that we obtain shareholder approval for certain dilutive events, such as an issuance that will result in a change of control, certain transactions other than a public offering involving issuances of 20% or greater interests in the company and certain acquisitions of the shares or assets of another company. While we do not currently intend to follow home country practice in lieu of the above requirements, we could decide in the future to follow home country practice and our board of directors could make such a decision to depart from such requirements by ordinary resolution.

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

We are a "controlled company" as defined under the Nasdaq Stock Market listing rules because Mr. Yi Zhang beneficially controls more than 50% of the total voting power of all issued and outstanding Ordinary Shares through the acting-in-concert arrangement under the Concert Party Agreement. As a result, Mr. Yi Zhang has the ability to control or significantly influence the outcome of matters requiring approval by shareholders. For the details of the Concert Party Agreement, see "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Agreement—Concert Party Agreement." In addition, for so long as we remain a controlled company under that definition, we are permitted to elect to rely on, and may rely on, certain exemptions from corporate governance rules, including an exemption from the rule that a majority of our board of directors must be independent directors. We do not currently plan to utilize the exemptions available for controlled companies, but instead, we plan to 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 are permitted to adopt 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 opt to rely on such exemptions in the future, such decision might afford less protection to holders of our ordinary shares." 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 weakness 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. 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 internal control over financial reporting ("ICFR"). Our management has not completed an assessment of the effectiveness of our internal control and procedures over financial reporting and our independent registered public accounting firm has not conducted an audit of our ICFR. In connection with the audit of our consolidated financial statements as of and for the three fiscal years ended March 31, 2023, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting as of March 31, 2023. 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 weakness identified relates to lack of sufficient competent financial reporting and accounting personnel with appropriate understanding of U.S. GAAP to design and implement formal period-end financial reporting policies and procedures to address complex U.S. GAAP technical accounting issues, and to prepare and review our consolidated financial statements and related disclosures in accordance with U.S. GAAP and financial reporting requirements set forth by the SEC. Neither we nor our independent registered public accounting firm had undertaken a comprehensive assessment of our internal control under the Sarbanes-Oxley Act for purposes of identifying and reporting material weaknesses and other control deficiencies in our ICFR. Had we performed a formal assessment of our ICFR or had our independent registered public accounting firm performed an audit of ICFR, additional deficiencies may have been identified.

To remediate our material identified material weakness, we adopted measures to improve our ICFR, including, among others: (i) hiring additional qualified accounting and financial personnel with appropriate knowledge and experience in U.S. GAAP accounting and SEC reporting, and (ii) organizing regular training for our accounting staffs, especially training related to U.S. GAAP and SEC reporting requirements. We also plan to adopt additional measures to improve our ICFR, including among others creating U.S. GAAP accounting policies and procedures manual, which will be maintained, reviewed and updated, on a regular basis, to the latest U.S. GAAP accounting standards, and further hiring executive accounting personnel with strong knowledge and experience in U.S. GAAP accounting and SEC reporting.

The implementation of these measures, however, may not fully address the material weakness identified in our ICFR, and we cannot conclude that it has been fully remedied. Our failure to correct the material weakness 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.

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.

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.

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 ending March 31, 2023, 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, including the cash acquired from Summit in the Business Combination. 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.

We may not be able to satisfy listing requirements of the Nasdaq Stock Market or obtain or maintain a listing of the Ordinary Shares on the Nasdaq Stock Market.

As the Ordinary Shares are listed on the Nasdaq Stock Market, we must meet certain financial and liquidity criteria to maintain such listing. If we violate the Nasdaq Stock Market's listing requirements, or if we fail to meet any of the Nasdaq Stock Market's 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 the Nasdaq Stock Market 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 profit or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay 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 founder, Mr. Yi Zhang, will have considerable influence over us and our corporate matters.

Our founder, Mr. Yi Zhang beneficially controls more than 50% of the total voting power of all issued and outstanding Ordinary Shares through the acting-in-concert arrangement under the Concert Party Agreement. As a result, Mr. Yi Zhang has considerable power to control actions that require shareholder approval under Cayman Islands law, such as approving any statutory merger pursuant to the Cayman Companies Act and amending our memorandum and articles of association. 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.

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 resale prospectus, effective on June 5, 2023, to facilitate the resale of our Ordinary Shares by the Selling Securityholders identified therein.

The sale of the Ordinary Shares in the public market or otherwise, including sales by us or the Selling Securityholders, 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, even if our business is doing well.

The securities registered for resale by the Selling Securityholders are subject to 180 days lock-up period from March 16, 2023. The lock-up requirements will cease to apply after the date on which the closing price of the Ordinary Shares equals or exceeds $12.00 per share for any 20 trading days within any 30 trading day period commencing at least 150 days after March 16, 2023. These shares will, upon expiration of such lock-up period, become eligible for resale without contractual restrictions. Following the expiration of the applicable lock-up and as restrictions on resale end and registration statements are available for use, the market price of the Ordinary Shares could continue to decline if the holders of restricted or locked up shares sell them or are perceived by the market as intending to sell them. As such, sales of a substantial number of the Ordinary Shares in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of the Ordinary Shares.

Despite a potential decline in the public trading price of the Ordinary Shares, certain securityholders, including certain Selling Securityholders, may still experience a positive rate of return on the securities that they sell as they have acquired the securities registered hereunder at prices substantially below current market prices, and may therefore have an incentive to sell their securities. Public securityholders who purchased our securities at higher prices than the Selling Securityholders may experience lower rates of return (if any) than the Selling Securityholders, due to differences in purchase price and the potential trading price at which they may be able to sell.

In addition, as of the date of this Annual Report, we have assumed our share incentive plan and the outstanding awards. We may grant additional options or share-based awards to employees, directors and consultants in the future. To the extent that any of these awards are vested and 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

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, Summit. As a result of and upon consummation of the Business Combination, the holders of shares and/or warrants of Summit has become the holders of our shares and/or warrant. The Business Combination was consummated on March 16, 2023. On March 17, 2023, the Ordinary Shares and Warrants commenced trading on The Nasdaq Stock Market LLC, under the symbols "YS" and "YSBPW," respectively.

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 https://www.ysbiopharma.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 website address is www.timschina.com. The information on, or that can be accessed through, our website is not part of this Annual Report.

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, YSJA™ rabies vaccine, which was the first aluminum-free lyophilized rabies vaccine launched in China. YSJA™ rabies vaccine significantly 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 other rabies vaccines in China. In addition, YSJA™ rabies vaccine is suitable for mass production and commercialization with long shelf life and low risk to contamination. As of the date of this Annual Report, approximately 98.0 million doses of YSJA™ rabies vaccine have been administered for post-exposure protection against rabies. With our track record of commercialization, YSJA™ rabies vaccine has achieved high production scalability and wide market recognition. Since we commenced the sales of YSJA™ rabies vaccine in October 2020 and up to March 31, 2023, we sold more than 19.9 million doses to 1,687 county-level CDCs in China, covering 58.5% of all county-level CDCs in China.

In addition to the commercialized YSJA™ 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 Annual Report, we have a portfolio of eight innovative product candidates: (1) four product candidates under various clinical development stages, including PIKA rabies vaccine, PIKA recombinant COVID-19 vaccine, PIKA YS-ON-001 and PIKA YS-HBV-001, and (2) four preclinical stage product candidates, targeting HBV, rabies, influenza and cancer with enormous medical demand. In addition, we are working on a series of therapeutic targets and products at the discovery stage. We have about 70 patents across more than 30 countries and regions relating to our PIKA immunomodulating technology and prophylactic and therapeutic product innovations. We believe our PIKA immunomodulating technology platform has the potential to nurture a wide variety of innovative vaccines and therapeutic biologics.

Our next-generation product candidate, PIKA rabies vaccine is a new generation rabies vaccine candidate that features accelerated seven-day regimen, fast seroconversion and broad protection against multiple virus strains. We have completed Phase I and Phase II clinical trial of PIKA rabies vaccine in Singapore, and completed Phase I study of PIKA rabies vaccine in China. The Phase I and II clinical studies to date have shown that PIKA rabies vaccine can be used under an accelerated regimen, which achieves a protective level of neutralizing antibodies as early as seven days post the first shot of vaccination and elicit more robust immunogenic response compared to that of the control arm vaccine, which is a widely used and commercially available vaccine. We believe that PIKA rabies vaccine has the potential to elevate the standard of care in post-exposure protection against rabies.

We completed the Phase II and III trials of PIKA recombinant COVID-19 vaccine in the Philippines and UAE. PIKA recombinant COVID-19 vaccine is composed of a PIKA adjuvant and trimeric recombinant full-length, wild-type SARS-CoV-2 spike glycoprotein optimized in the established CHO expression system. We completed Phase I trial of PIKA recombinant COVID-19 vaccine in the UAE in the first half of 2022, and the preliminary results showed that as basic immunization and sequential booster immunization, PIKA recombinant COVID-19 vaccines can induce the production of high-level neutralizing antibodies, which are effective for a variety of mutant strains, including Delta, Omicron sublineages BA.1, BA.2, BA.3, BA.4/5 and BA 2.12.1. In November 2022, we obtained the clearance of Investigational New Drug Application (“IND”) for PIKA recombinant COVID-19 vaccine from FDA in the United States. We are currently evaluating the evolvement of COVID-19 pandemic, monitoring global health trends, and evaluating market dynamics in order to make appropriate decisions in regard to the optimal commercialization strategies for PIKA recombinant COVID-19 vaccine.

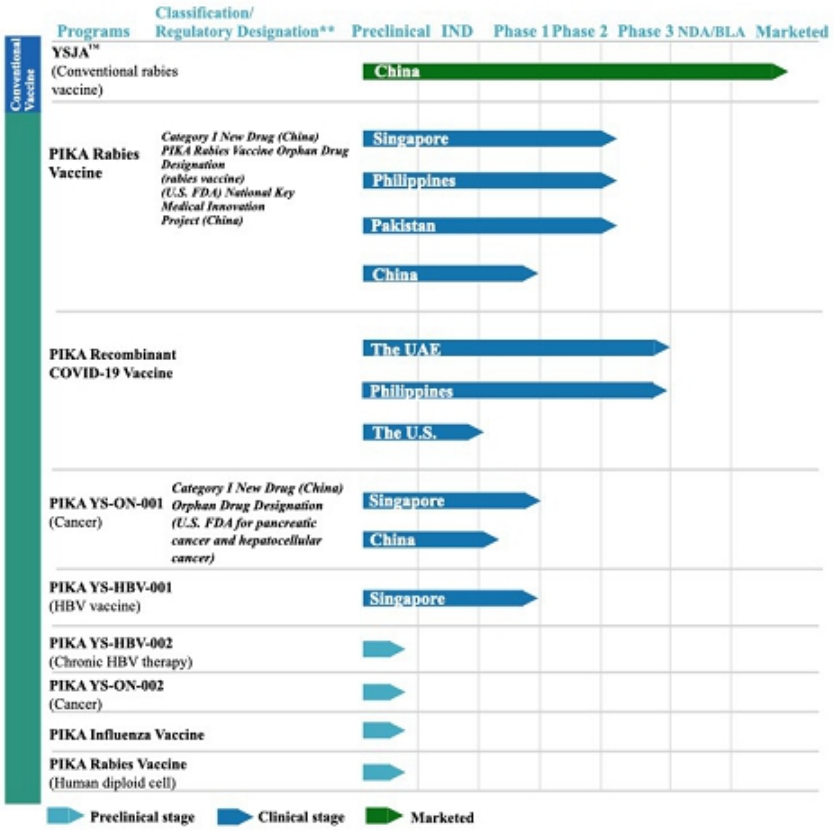
We have been manufacturing YSJA™ rabies vaccine and clinical trial samples of clinical candidates in our current GMP-compliant facilities. We have also obtained patents in relation to our manufacturing techniques and devices. Our current manufacturing facilities have an annual production capacity of approximately 15 million doses of YSJA™ rabies vaccine. We have a comprehensive and highly effective commercialization infrastructure, underpinned by our experienced in-house commercialization team and professional service providers. As of March 31, 2023, our in-house commercialization team managed our sales and marketing activities across 329 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, YSJA™ 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.

Overview

Our portfolio consists of nine biologics, including one marketed product, four clinical-stage candidates and four 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.



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.

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.

YSJA™ Rabies Vaccine — Our marketed product

YSJA™ rabies vaccine is an aluminum-free, inactivated Vero cell based vaccine, which is the first aluminum-free lyophilized rabies vaccine developed in China. Since its launch in 2003, approximately 98 million doses have been administered to patients for post-exposure protection against rabies. YSJA™ 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 YSJA™ rabies vaccine in February 2020 and its sales in October 2020. Since October 2020 and up to March 31, 2023, we sold more than 19.9 million doses of YSJA™ rabies vaccines to 1,687 county-level CDCs in China.

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.

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 290 in 2019, out of which the number of deaths was 744 and 276 in 2015 and 2019, 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, a CAGR of 8.5% from 2025 to 2030.

Advantages

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

- *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 97 or 98 million doses of YSJA™ rabies vaccine have been administered in China.

- *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.

- *Better safety profile*. According to a head-to-head study, the administration of YSJA™ rabies vaccine causes less pain and injection site discomfort to patients. YSJA™ 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 YSJA 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:

(1) A head-to-head clinical study conducted by Guangxi CDC center in China to evaluate adverse reactions of YSJA 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 YSJA 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 YSJA 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 YSJA rabies vaccine for children under 10 years old, especially under 3 years old to reduce the incidents of adverse reactions.

(2) A head-to-head clinical study conducted by Guizhou CDC center in China to evaluate adverse reactions and immune response of YSJA 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 YSJA 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 YSJA 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 YSJA rabies vaccine was lower and the seroconversion rate was higher comparing to those of the other leading product.

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

The trial enrolled 206 post-exposure patients including 102 subjects and 104 subjects receiving YSJA 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 YSJA rabies vaccine 8.82%. The difference was statistically significant ($P<0.01$). The study recommends using YSJA rabies vaccine as the first choice due to its lower rate of adverse reactions.

(4) A head-to-head clinical study conducted by Yiwu CDC center in Zhejiang, China to evaluate adverse reactions of YSJA 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 YSJA 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 YSJA 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 YSJA 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 YSJA rabies vaccine and the imported lyophilized rabies vaccine in terms of the adverse reaction rate and seroconversion rate but YSJA 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 YSJA™ rabies vaccine offers several advantages in terms of mass production, such as:

- *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.

- *Established product profile*. Approximately 97 million doses of YSJA™ 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).

- *Enhanced convenience and stability*. YSJA™ 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.

- *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

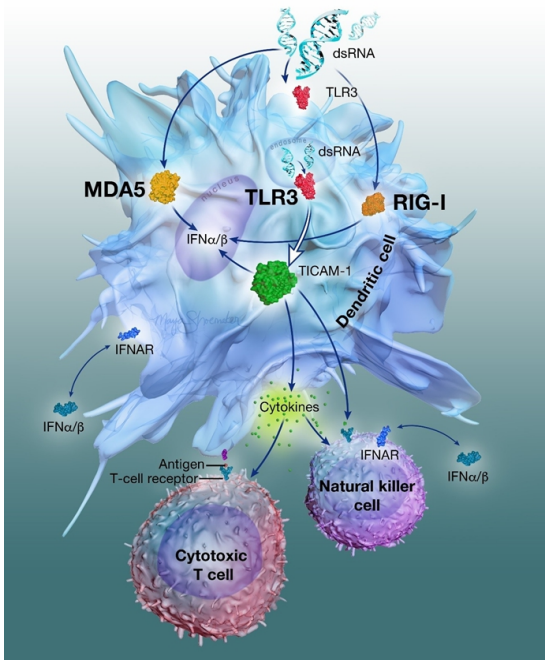
We received the GMP certificate for our manufacturing facilities in Shenyang, China in July 2019, pursuant to which we started the production of YSJA™ rabies vaccine in February 2020 and the sales in October 2020. In the three fiscal years ended March 31, 2023, we sold more than 19.9 million doses to 1687 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 2,071 in China.

To expand our international market operation, we also seek potential partnership and licensing with leading pharmaceutical companies to commercialize YSJA™ rabies vaccine in certain international market. We intend to expand our commercialization efforts into countries throughout Asia, Middle East, Europe, North, Central and South America.

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



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 YSJA™ 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 NDA. This vaccine candidate was designated by a WHO expert committee background paper publication as an innovative rabies vaccine.

We received approval of Phase III clinical trials of PIKA Rabies vaccine from the regulatory authorities in the Philippines, Singapore and Pakistan. We intend to start the trial in 2023. This Phase III study is a multi-center multi-country study to be conducted in Singapore, Philippines and Pakistan. In China, we completed Phase I study of PIKA rabies vaccine and preliminary results confirm the dose, regimen and safety observed from the Singapore trials. We are planning to discuss with NMPA in 2023 and launch more advanced trials in China afterward. Upon completion of successful Phase III trials in the relevant countries, we plan to submit the NDA/BLA for PIKA rabies vaccine to the regulatory authorities in countries throughout Asia, Africa, the Middle East, Europe, and North, Central and South America.

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 "—YSJA™ 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 is entering 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.

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 in multiple Southeast Asian countries, which is expected to be conducted in 2023; and

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

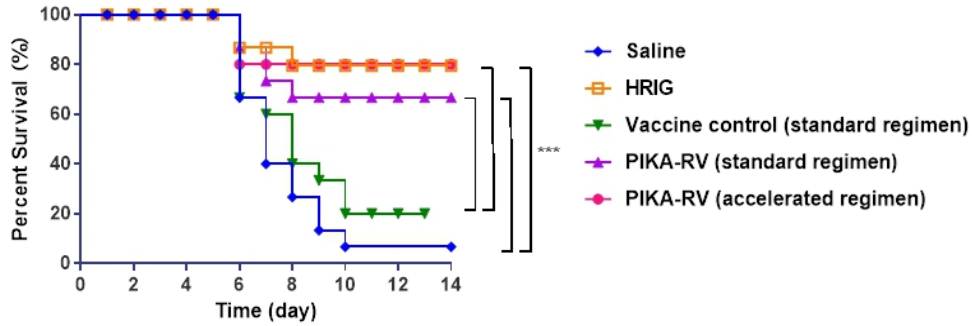
We received the approval of Phase III clinical trials of PIKA Rabies vaccine from the regulatory authorities in the Philippines, Singapore and Pakistan. We intend to start the trial in 2023. This Phase III study is a multi-center multi-country study to be conducted in Singapore, Philippines and Pakistan. 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.

We expect to conduct the pivotal Phase III clinical trials in Southeast Asia in healthy volunteers without exposure to animal bite, which are estimated to be approximately 4,500 subjects in total, in 2023. We plan to discuss with NMPA in 2023 and launch more advanced trials in China afterward. Upon completion of successful Phase III trials in the relevant countries, we plan to submit the NDA/BLA for PIKA rabies vaccine to the regulatory authorities in countries throughout Asia, Africa, the Middle East, Europe, and North, Central and South America.

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



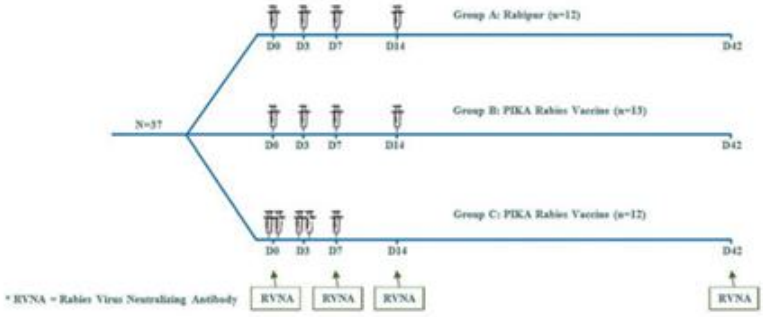
Significant difference between survival curves was determined by the Chi-square test (***$p < 0.005$). There is no significant difference between the groups not marked.

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.

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.

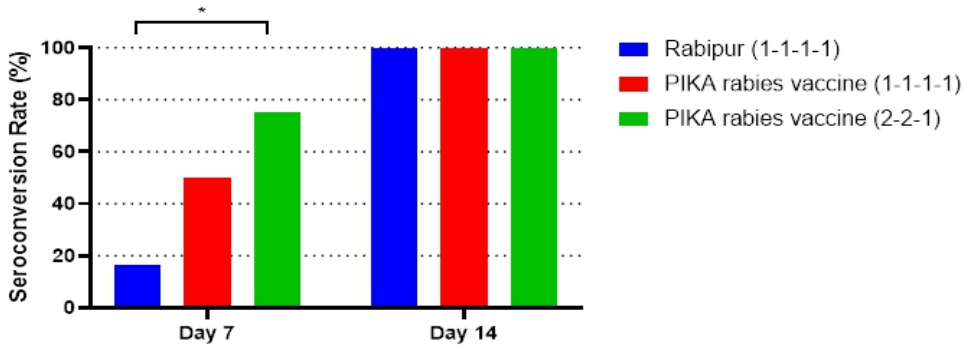
Figure 3



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.

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)



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.

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 (-2.67, 22.11)	12.07 ± 10.07 (-0.31, 24.46)	20.06 ± 33.12 (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

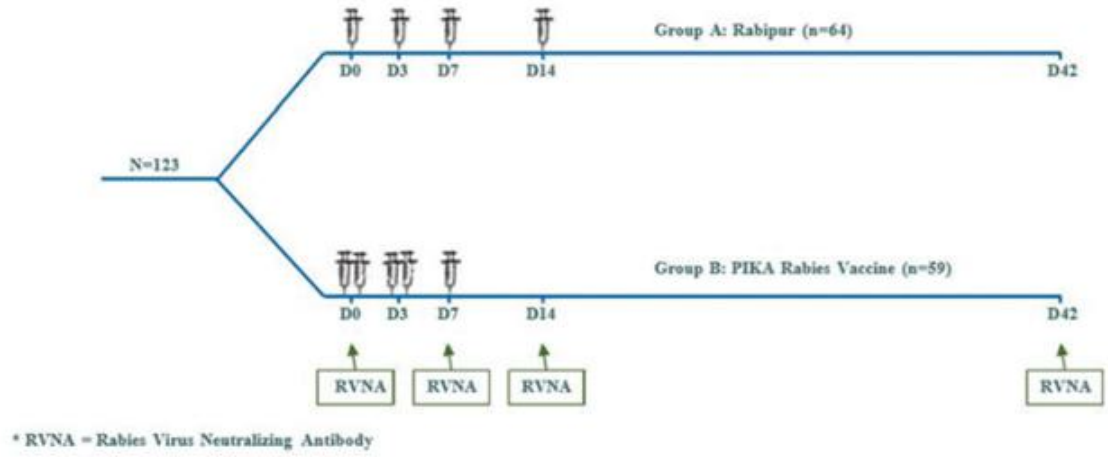
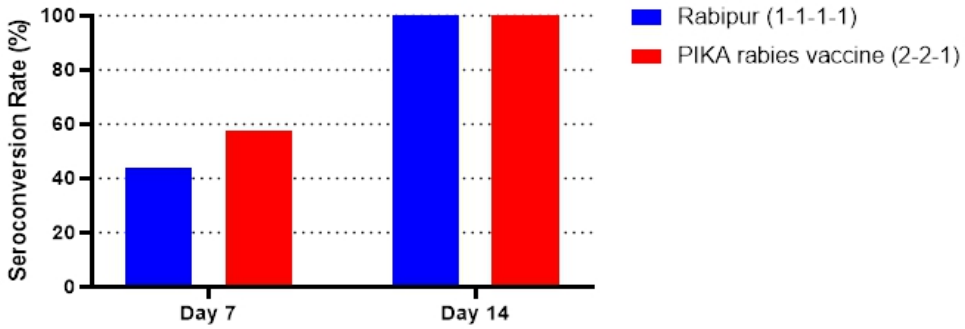


Figure 6. Percentage of subjects with protective serum neutralizing antibodies

(≥0.5 IU/mL)



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

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.

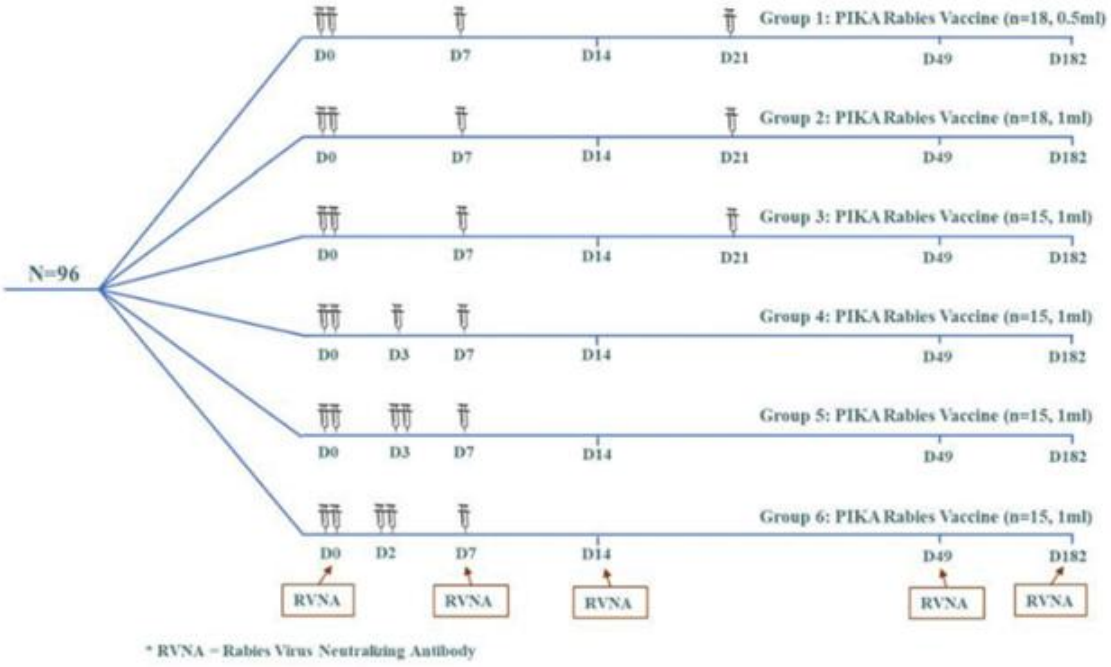
The accelerated regimen of PIKA rabies vaccine is advantageous to the standard Zagreb or Essen regimens because the standard regimens fail to induce higher and earlier seroconversion at day 7 post vaccination. Since the incubation period of rabies is approximately two or three months, our future clinical 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



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.

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 Southeast Asian Countries

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 will be a multi-center, multi-country trial in Singapore, Philippines and Pakistan, which is planned to start in 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 subjects will be enrolled in the study randomized 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

Treatment Allocation

Group	Vaccine	Regimen	Study Days of Vaccination					N
			0	3	7	14	28	
1	PIKA Rabies Vaccine lot#1	2-2-1	XX	XX	X	O	O	1000
2	PIKA Rabies Vaccine lot#2	2-2-1	XX	XX	X	O	O	1000
3	PIKA Rabies Vaccine lot#3	2-2-1	XX	XX	X	O	O	1000
4	Comparator	1-1-1-1-1	XO	XO	X	X	X	1500
Total								4500

PIKA Recombinant COVID-19 Vaccine (injectable)

We began to develop in-house PIKA YS-SC2-010, also known as PIKA recombinant COVID-19 vaccine, in 2020. PIKA recombinant COVID-19 vaccine is being developed for the indication to have both prophylactic and therapeutic effects against COVID-19 disease caused by SARS-CoV-2, which is composed of our proprietary PIKA adjuvant and recombinant trimeric SARS-CoV-2 spike (S) protein subunit antigen (CHO cells). Preclinical studies results have demonstrated that PIKA recombinant COVID-19 vaccine achieved rapid, long-lasting and broad immune response against SARS-CoV-2. Compared with other COVID-19 vaccines with published data, PIKA COVID-19 vaccine can produce high-level antibodies 14 days after the initial immunization, while other vaccines generally need 3-6 weeks after the initial immunization to induce antibody production. By day 596 post prime vaccination, antibodies elicited by PIKA recombinant COVID-19 vaccine continued to effectively neutralize circulating variants SARS-CoV-2, including D614G, B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.617.2 (Delta) and B.1.1.529 (Omicron). Cynomolgus monkey study results also showed both prophylactic and therapeutic effects against SARS-CoV-2. PIKA YS-SC2-010 has exhibited significant inhibition against virus replication with important treatment effect. We submitted the IND application for the prophylactic and therapeutic PIKA recombinant COVID-19 vaccine as a prophylactic vaccine to regulatory authorities of multiple jurisdictions, including Singapore, in 2021. We completed Phase I trial of PIKA recombinant COVID-19 vaccine in the UAE in the first half of 2022 and the preliminary results showed that as basic immunization and sequential booster immunization, PIKA recombinant COVID-19 vaccines can induce the production of high-level neutralizing antibodies, which are effective for a variety of mutant strains, including Delta, Omicron sublineages BA.1, BA.2, BA.3, BA.4/5 and BA 2.12.1. In November 2022, we obtained the clearance of IND for PIKA recombinant COVID-19 vaccine from FDA in the United States. We have completed of the enrollment of the multi-center multi-country Phase II/III clinical trials in the Philippines and UAE. The interim data analysis of Phase II study presented that the trial met both primary and secondary endpoints, measured by geometric mean titers (GMTs) of neutralizing antibody against Omicron virus and by seroconversion rates on Day 7 and Day 14 post a booster dose administration. We are currently evaluating the evolvement of COVID-19 pandemic and will make appropriate decision on the commercialization strategy in due course.

Mechanism of action

Historically, vaccine-induced protective immunity has been largely attributed to the function of antibodies, especially neutralizing antibodies that block the entry of the virus into target host cells and thus prevent infection. Due to their capabilities of providing immediate protection upon exposure, the elicitation of neutralizing antibodies has long been the primary goal of vaccination against many pathogens, including SARS-CoV-2. The immune responses to SARS-CoV-2 involve innate immune activation and antigen-specific responses of B and T cells.

PIKA recombinant COVID-19 vaccine's antigen component is a recombinant full-length, wild-type SARS- CoV-2 spike glycoprotein optimized in the established CHO expression system. The major target of neutralizing antibodies to SARS-CoV-2 is the S protein consisting of S1 and S2 domains. S1 is membrane distal and contains the receptor binding domain (RBD) that binds to the cellular receptor ACE2. S2 is membrane proximal and plays a role in membrane fusion. Antibodies binding to the S1 RBD can block interaction with ACE2 and antibodies binding to the S2 can inhibit conformation changes of the S protein and block membrane fusion. Therefore, the majority of COVID-19 vaccine candidates under preclinical and clinical development use the full-length S protein. To stabilize the full-length spike protein of SARS-CoV-2, we made two modifications to the S protein sequence, including the modification of S1/S2 furin cleavage site 682-RRAR-685 to 682-GSAS-685 and the introduction of two proline substitutions at positions K986P and V987P.

PIKA recombinant COVID-19 vaccine contains PIKA adjuvant which is used to enhance and prolong both antibody and cellular immunity and ultimately provide durable protective effect. According to a recent challenge study in non-human primates, potent and durable neutralizing antibodies play an important protective role, and CD8+ T cell responses also contribute to protection especially when the antibody responses are suboptimal. In several late-stage clinical trials, S protein-based vaccines in mRNA and viral vector-based platforms have shown excellent preliminary vaccine efficacy against multiple SARS-COV-2 variants.

Market opportunities and competition

According to the WHO there are 14 vaccines approved for use by WHO, NMPA, FDA or emergency approval, and 70 COVID-19 vaccines in clinical Phase III and above as of July 31, 2022. According to a study from John Hopkins University herd immunity of COVID-19 could be achieved when 70% to 90% of the population acquire immunity. Assuming that an individual needs an average of two doses of COVID-19 vaccine to achieve immunity, a corresponding total of 10.5 to 13.5 billion doses and 2.0 to 2.5 billion doses of COVID-19 vaccines are required to achieve herd immunity globally and in China, respectively. On May 5, 2023, the head of the WHO declared "with great hope" an end to COVID-19 as public health emergency, stressing that it does not mean the disease is no longer a global threat. We are currently evaluating the evolvement of COVID-19 pandemic and will make appropriate decision on our commercialization strategies of PIKA COVID-19 vaccine.

WHO label	Pango lineage	GISAID clade/lineage	Nextstrain clade	Earliest documented samples	Date of designation
			VOCs(1)		
Alpha	B.1.1.7	GRY (formerly GR/50lY.Vl)	20I (Vl)	The United Kingdom, September 2020	December 18, 2020
Beta	B.1.351	GH/501Y.V2	20H (V2)	South Africa, May 2020	December 18, 2020
Gamma	P.1	GR/501Y.V3	20J (V3)	Brazil, November 2020	January 11, 2021
Delta	B.1.617.2	G/478K.V1	21A	India, October 2020	VOI: April 4, 2021 VOC: May 11, 2021
			VOCs(2)		
Epsilon	B.1.427/B.1.429	GH/452R.Vl	21C	The U.S., March 2020	March 5, 2021
Zeta	P.2	GR/484K.V2	20B	Brazil, April 2020	March 17, 2021
Et.a	B.1.525	G/484K.V3	21D	Multiple countries, December 2020	March 17, 2021
Theta	P.3	GR/1092K.Vl	21E	Philippines, January 2021	March 24, 2021
Iota	B.1.526	GH/253G.Vl	21F	The U.S., November 2020	March 24, 2021
Kappa	B.1.617.1	G/452R.V3	21B	India, October 2020	April 4, 2021
Lambda	C.37	GR/452Q.Vl	20D	Peru, August 2020	June 14, 2021

(1) A SARS-CoV-2 variant is a VOC if it meets the definition of a VOI and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance: (i) increase in transmissibility or detrimental change in COVID-19 epidemiology; or increase in virulence or change in clinical disease presentation; and/or (ii) decrease in effectiveness of public health and social measures or available diagnostics, vaccines and therapeutics.

(2) (A SARS-CoV-2 isolate is a VOI if, compared to a reference isolate, its genome has mutations with established or suspected phenotypic implications, and either: (i) has been identified to cause community transmission/multiple COVID-19 cases/clusters, or has been detected in multiple countries; or (ii) is otherwise assessed to be a VOI by the WHO in consultation with the WHO SARS-CoV-2 Virus Evolution Working Group.

Source: the WHO

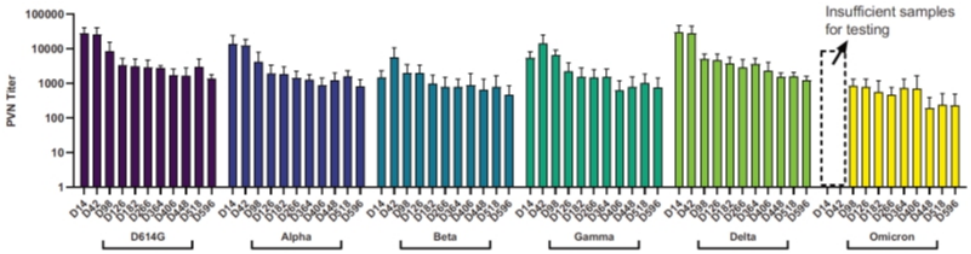
Advantages

PIKA recombinant COVID-19 vaccine is an innovative vaccine candidate against multiple SARS-COV-2 variants. PIKA recombinant COVID-19 vaccine is composed of our proprietary PIKA adjuvant and recombinant trimeric SARS-CoV-2 spike (S) protein subunit antigen (CHO cells). It is made by using genetically engineered recombinant CHO cells, which are cultured, harvested, concentrated and purified to obtain S-trimer protein designed according to the structure of S-protein of SARS-CoV-2 virus, and added with appropriate stabilizer and PIKA adjuvant. The production process of PIKA recombinant COVID-19 vaccine relies on mature genetic engineering technology of recombinant protein, which is highly scalable and poses low biosafety risk.

Preclinical studies results demonstrated that PIKA recombinant COVID-19 vaccine has rapid and efficient production of neutralizing antibody and cellular immunity to provide quick and sustained protection, with the titer of neutralizing antibodies against pseudovirus and wild-type SARS-CoV-2 virus induced by vaccine being up to 104, which shows a good immune effect. Moreover, the neutralizing antibodies induced by PIKA recombinant COVID-19 vaccine can persist for at least 596 days post-immunization, indicating a good durability of the immune response. The results of prophylaxis animal challenge tests have shown that the PIKA recombinant COVID-19 vaccine could significantly inhibit virus replication and relieve the inflammation in lungs. In addition, PIKA recombinant COVID-19 vaccine can significantly enhance the antigen-specific cellular immune response and convert the Th2-bias immune response to the Th1-bias immune response, decreasing the risk of antibody dependent enhancement.

PIKA recombinant COVID-19 vaccine is effective against the currently prevalent mutant strains, in particular multiple virus variants of SARS-CoV-2, including D614G, B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.617.2 (Delta) and B.1.1.529 (Omicron). As indicated in Figure 13, neutralizing antibodies measured at day 14, 42, 98, 126, 182, 266, 364,406, 448, 518 and 596 post prime vaccination in New Zealand rabbit study demonstrated rapid, efficient, sustainable and high protection against multiple virus variants of SARS-CoV-2.

Figure 9. Neutralizing antibodies against multiple virus variants of SARS-CoV-2 in New Zealand rabbit study



In terms of therapeutic effect, previous studies have shown that type I IFN response and T cell response may be crucial for the control and recovery of SARS-CoV-2 infection. Therefore, the rapid induction of SARS-CoV-2 specific T cell immune response in the early stage of infection may effectively alleviate the symptoms of COVID-19 patients and accelerate the recovery process. The results of cellular immune response demonstrated that PIKA recombinant COVID-19 vaccine can promote the early antigen-specific T cell immune response, which may play a role in alleviating the symptoms of COVID-19 patients and accelerating the recovery process. In a non-human primates study, vaccinated groups had significantly lower viral load than the control group, which indicates that vaccination using PIKA recombinant COVID-19 vaccine can significantly inhibit virus replication and demonstrates significant treatment effect. The results of therapeutic animal challenge tests have also demonstrated that recombinant COVID-19 vaccine could significantly reduce the viral load of the lung.

Based on the results of our controlled animal studies (not head-to-head), we observed that PIKA recombinant COVID-19 vaccine, once marketed, may have the following characteristics and advantages:

- *High level of neutralizing antibodies*. PIKA recombinant COVID-19 vaccine generated a high level of neutralizing antibodies. It has demonstrated a high level of neutralizing antibody activities against the SARS-CoV-2 virus as discussed above.

- *Sustainable antibody response*. PIKA recombinant COVID-19 vaccine generated sustainable neutralizing antibodies against the original virus strain and most of the currently prevalent mutant strains of the SARS-Cov-2 virus at post prime vaccination on day 14, 42, 98, 126, 182, 266, 364, 406, 448, 518 and 596.

- *Broad range of protection against mutant virus strains*. PIKA recombinant COVID-19 vaccine demonstrated strong response to a broad range of mutant SARS-CoV-2 virus strains currently prevalent in the world, including but not limited to D614G, B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.617.2 (Delta) and B.1.1.529 (Omicron).

- *Rapid production of antibodies and protection against multiple SARS-COV-2 variants*. PIKA recombinant COVID-19 vaccine has the potential to be administered in two doses with a relatively short interval and enables the rapid and high production of antibodies, which is particular important during a highly transmissible infection.

- *Broad and balanced Th1, Th2 immune response*. PIKA recombinant COVID-19 vaccine has the potential to generate strong CD4+ and CD8+ T-cell responses, which may provide protection especially in the case of weak antibody responses. Moreover, balanced Th1 and Th2 immune responses could be elicited by PIKA recombinant COVID-19 vaccine, which may decrease the risk of antibody dependent enhancement.

- *Unique therapeutic benefit*. PIKA recombinant COVID-19 vaccine exhibits promising treatment benefit in animal studies, which has the potential to become a therapeutic vaccine against the virus.

- *Versatile recombinant vaccine for mass production.* With a universal profile to induce stronger and broader range of sustainable and high neutralizing antibody response rate against existing and emerging variants, PIKA recombinant COVID-19 vaccine has the potential to achieve economy of scale which is considerably more suitable for mass production.

- *Favorable storage condition.* PIKA recombinant COVID-19 vaccine has the potential to be stored at a temperature between 2°C and 8°C, which is much higher and easier to achieve than that of other COVID-19 vaccines requiring lower storage temperatures.

- *Expanded coverage of vaccination.* Inclusion of PIKA has the potential to decrease the amount of spike protein antigen and expand the coverage of vaccination among the general population.

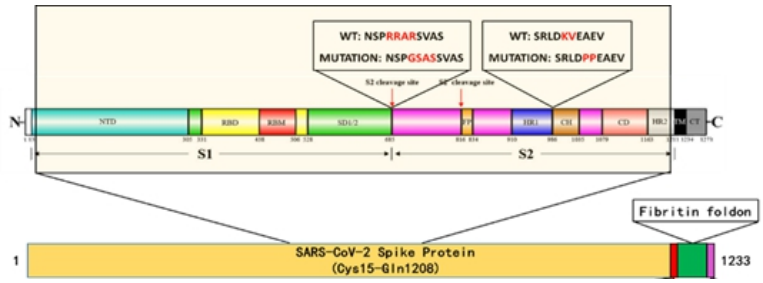
The results from preclinical studies and early stage clinical trials of PIKA recombinant COVID-19 vaccine may not be predictive of the results of later-stage clinical trials.

Summary of Preclinical Results

Full-length Spike Protein modification

The recombinant full-length spike protein is produced using CHO cell expressing system. It is the trimeric S protein that binds to the ACE2 receptor on host cells and mediates the entry of SARS-CoV-2 into the cells. To generate a stable prefusion S trimeric protein structure, several modifications were made, including (1) inserting fibritin foldon (Fd) domain of T4 bacteriophage fibritin protein at the C-terminal of the S protein, which can assist correct assembling and folding of trimerization and stabilize the natural trimer conformation; (2) mutating the Furin restriction site between S1/S2 (RRAR to GSAS, 682-685) to obtain stable prefusion conformation; and (3) inserting two prolines (K986P and V987P) to make S protein more stable. The schematic representation of the structure is shown below.

Figure 10. Schematic Representation of S Trimeric Protein Structure

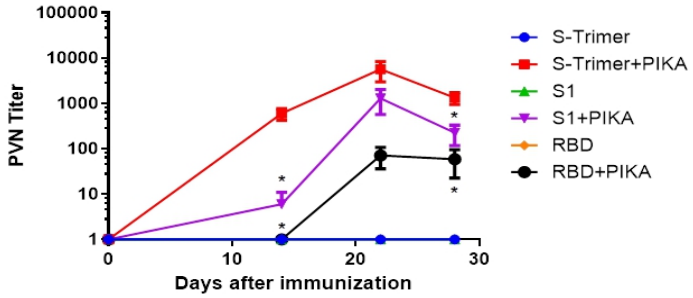


Antigen selection

To employ the best antigen for further development, we produced three antigens, including full-length S-Trimer protein, S1 domain protein, and RBD. We immunized New Zealand rabbits intramuscularly with 6 ug of each antigen, with and without PIKA adjuvant for three times with one week apart.

The results demonstrated that antigen alone without PIKA adjuvant, regardless of the type of antigen, either failed to induce, or induced, modest level of neutralizing antibodies against pseudovirus. In contrast, antigen with PIKA adjuvant significantly enhanced the level of neutralizing antibodies. Among the three antigens, S-trimer performed the best in terms of neutralizing antibody production. We also measured the level of neutralizing antibodies production against wild-type SARS-CoV-2 virus. S-Trimer with PIKA adjuvant elicited higher level of neutralizing antibodies than RBD with PIKA adjuvant.

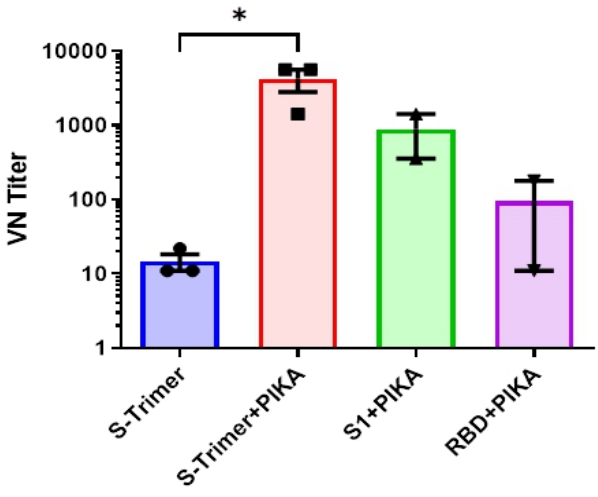
Figure 11. Level of neutralizing antibodies against pseudovirus in New Zealand rabbits immunized with S-Trimer, S1 protein and RBD



Data are shown as mean ± SEM. *p*-values were analyzed with a two-way ANOVA (vs. S-Trimer + PIKA, *$p < 0.05$). There is no significant difference between the PIKA adjuvanted groups which were not marked at the same timepoint.

Pharmaceutical research is an evidence-based science aiming to apply scientific information retrieved from research experiments and to seek to assess the quality of research results, data or evidence relevant to the risks and benefits of individuals' characteristics or treatments. A statistic approach based on P-value is a common methodology in evaluating such research. A p-value, or probability value, is a number describing how likely it is that your data would have occurred by chance (i.e., that the null hypothesis is true). The level of statistical significance is often expressed as a p-value between 0 and 1. The smaller the p-value, the stronger the evidence you should reject the null hypothesis. In terms of applying statistical science in the biomedical research, the p-value is the probability of obtaining a result at least as extreme as the one that was observed in the biological or clinical experiment or epidemiological study, given that the null hypothesis is true. The "P" value, frequently used to measure statistical significance, is the probability that the study results are due to chance rather than to a real treatment effect. Conventionally, $p < 0.05$ is referred as statistically significant and $p < 0.001$ as statistically highly significant. In medical research, p values less than 0.05 are often reported as statistically significant as it is wanted want there to be only a 5% or less probability that the treatment results, risk factor, or diagnostic results could be due to chance alone. Results that do not meet this threshold are generally interpreted as negative. There is no direct relevance of the statistical significance of such results to evidentiary standard of drug approval, as such statistical results were just a small component of decision-making process by the regulatory organization, and the drug approval process requires substantially more evidence from scientific research to comprehensive clinical studies to product manufacturing qualification measures.

Figure 12. Level of neutralizing antibodies against wild-type SARS-CoV-2 virus in New Zealand rabbits immunized with S-Trimer, S1 protein and RBD

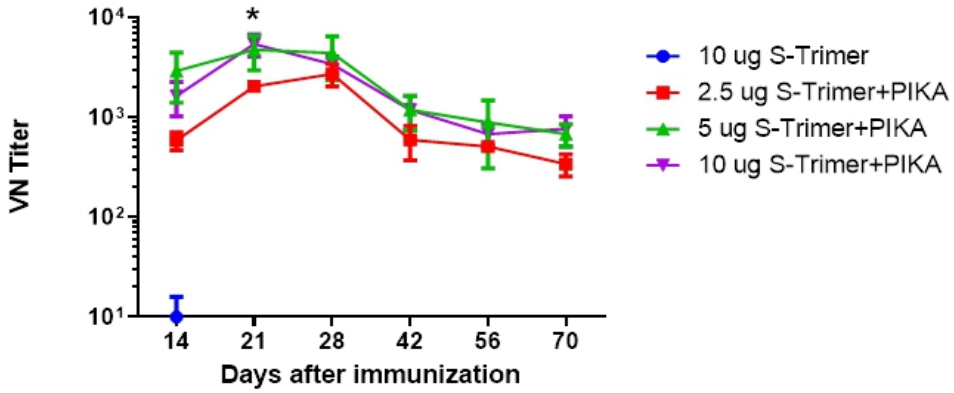


Data are shown as mean ± SEM. *p*-values were analyzed with a one-way ANOVA (*$p < 0.05$). There is no significant difference between the groups not marked.

Dose exploration

As the next step, we explored the different dose levels of S-trimer with PIKA adjuvant and assessed the kinetic of neutralizing antibody against pseudovirus. Antigen alone even at the highest dose elicited modest level of antibodies. When PIKA adjuvant was added to S-trimer at dose level of 2.5 ug, 5 ug and 10 ug, all three elicited high levels of neutralizing antibodies, with the level of antibodies induced by 2.5 ug of S-trimer slightly lower and 5 ug and 10 ug of S-Trimer induced comparable level of antibodies.

Figure 13. Level of neutralizing antibodies against pseudovirus in New Zealand rabbits immunized with escalating dose of S-Trimer protein with or without PIKA adjuvant

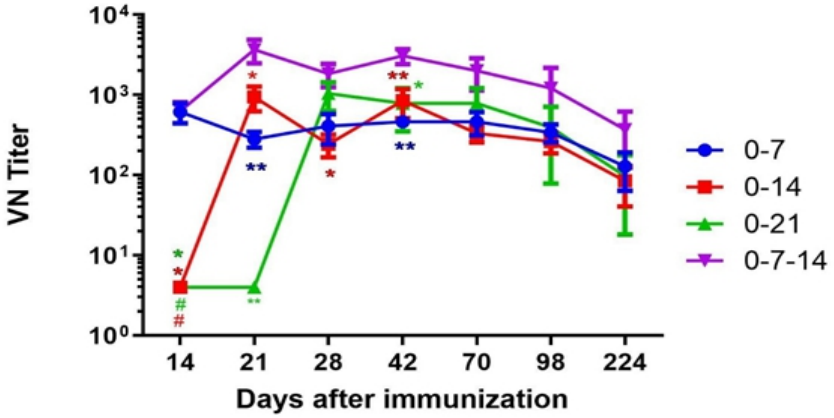


Data are shown as mean ± SEM. *p*-values were analyzed with a two-way ANOVA (2.5 μg of S-Trimer + PIKA compared with 10 μg S-Trimer + PIKA, *$p < 0.05$). There is no significant difference between the PIKA adjuvanted groups which were not marked at the same timepoint.

Dosing schedule exploration

To optimize the dosing regimen, we immunized New Zealand rabbits with 5 ug of S-Trimer and 1 mg of PIKA adjuvant using four different dosing schedules, including three two-dose regimens at day 0 and day 7, day 0 and day 14, and day 0 and day 21, and one three-dose regimen at day 0, day 7 and day 14. We measured neutralizing antibodies against wild-type SARS-CoV-2 virus. The three-dose regimen at day 0-7-14 dosing schedule performed best while the three two-dose regimens elicited comparable level antibodies after day 42. The day 0-7 dosing schedule rapidly elicited high level of antibodies one week after the second dose, which could be advantageous as urgent control during the COVID-19 pandemic.

Figure 14. Level of neutralizing antibodies against wild-type SARS-CoV-2 virus in New Zealand rabbits immunized with S-Trimer with PIKA adjuvant at different dosing schedules

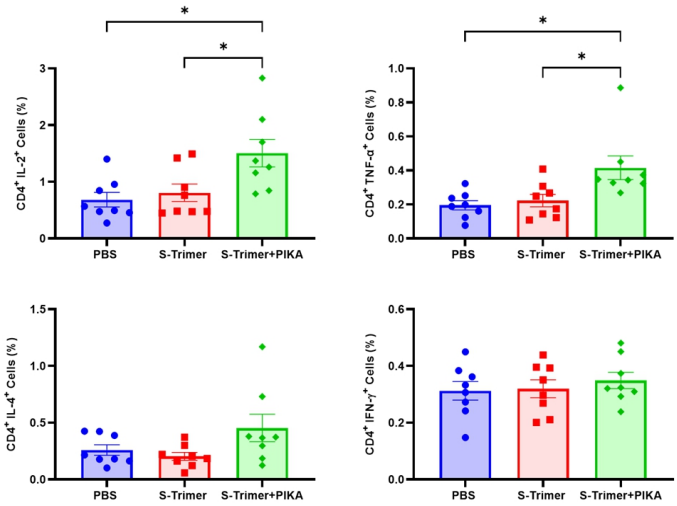


Data are shown as mean ± SEM. *P*-values were analyzed with a two-way ANOVA (vs. 0-7-14 group, *p < 0.05, **p < 0.01; vs. 0-7 group, #p < 0.05).

Th1 and Th2 cellular immunity

Antibody dependent enhancement is a risk associated with COVID-19 vaccines. A Th2 dominant cellular immune response is considered contributing factor of antibody dependent enhancement. A balanced Th1/Th2 cellular immune response is preferred to Th1 cellular immune response to decrease the risk of antibody dependent enhancement. We analyzed the T cells expressing Th1 and Th2 typed cytokines (IL2-vs. IL-4) by intracellular cytokine staining. The results suggest PIKA recombinant COVID-19 vaccine induced a balanced Th1 and Th2 cellular immune response.

Figure 15. T cells expressing Th1 (IFN', IL-2) and Th2 (IL-4, TNF) type cytokines in Balb/C mice immunized with S-Trimer with or without PIKA adjuvanton Days 0, 7 and 14

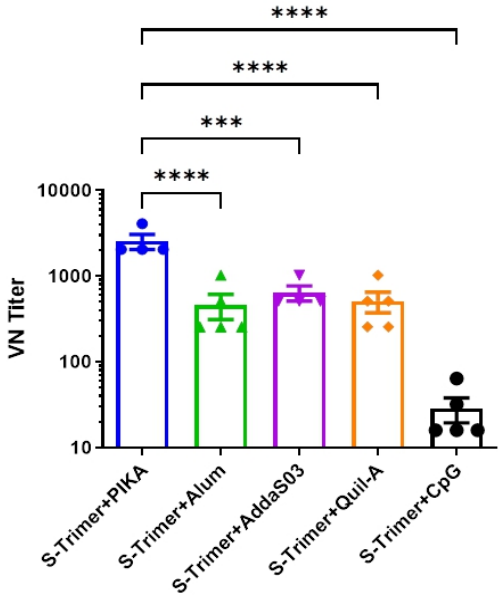


Data are shown as mean ± SEM. *p*-values were analyzed with a one-way ANOVA (*$p < 0.05$). There is no significant difference between the groups not marked.

S-Trimer immunogenicity

PIKA adjuvant is superior to other types of adjuvants in augmenting S-Trimer immunogenicity. Groups of New Zealand rabbits were immunized on days 0 and 7 with 5 ug S-Trimer in combination with different adjuvants including Alum, AddaSO3, Quil-adjuvant, and CpG. We measured wild-type SARS-CoV-2 neutralizing antibodies 14 days after initial immunization. The results have indicated that PIKA performed best in terms of adjuvanting S-Trimer antigen.

Figure 16. Wild-type SARS-CoV-2 virus neutralizing antibodies in animal serum at day 14 post-immunization in New Zealand rabbits immunized with S-Trimer in combination with different adjuvants

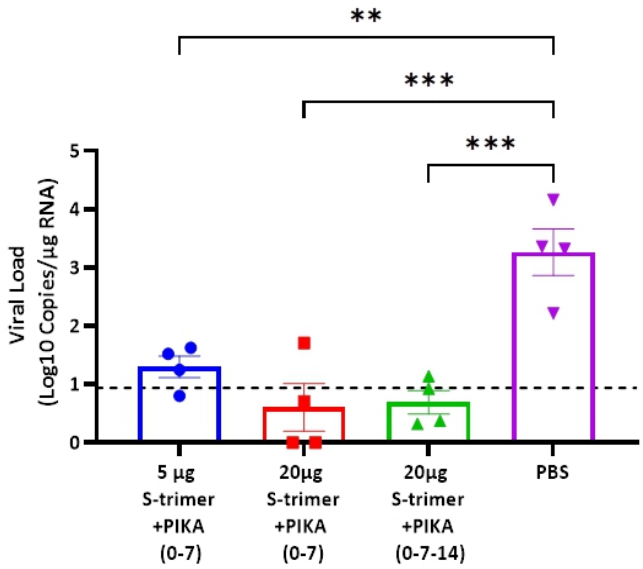


Data are shown as mean ± SEM. *p*-values were analyzed with a one-way ANOVA (***$p < 0.001$, ****$p < 0.0001$). There is no significant difference between the groups not marked.

Protective activity

To demonstrate the protective activity of PIKA recombinant COVID-19 vaccine, 16 cynomolgus monkeys were randomly divided into four groups, among which the control group, the low-dose group and the high-dose group 1 adopted immunization regimen 0-7 (that is, immunized once each day on day 0 and day 7); while the high-dose group 2 adopted immunization regimen 0-7-14 (that is, immunized once each day on day 0, day 7 and day 14). All four treatment groups were challenge tested with COVID-19 (SARS-CoV-2) 7 days after the last immunization. As indicated below, the result of the monkey study has shown that the three vaccinated groups had significantly lower viral load than the control group, which means that vaccination using PIKA recombinant COVID-19 vaccine can significantly inhibit virus replication and demonstrates good preventive effect. In addition, viral load decrease is correlated with the dose: the higher the antigen dose, the more times the monkeys receive immunization, and the further decrease in viral load.

Figure 17. COVID-19 viral load in the lungs of cynomolgus monkeys 7 days after challenge

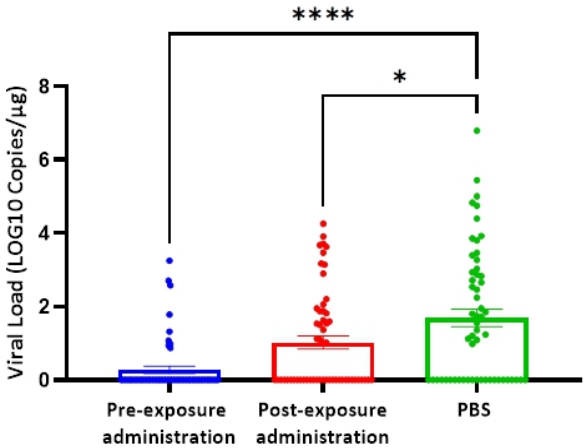


Data are shown as mean ± SEM. The horizontal dashed line indicates the limit of detection. Significance was calculated using one-way ANOVA (**p < 0.01; ***p < 0.001). There is no significant difference between the groups not marked.

Therapeutic activity

To demonstrate the therapeutic activity of PIKA recombinant COVID-19, 12 cynomolgus monkeys were randomly divided into three groups, including pre-exposure, post-exposure and controlled groups. The control group and the pre-exposure dosing group were dosed every day from the fifth day prior to the challenge, attacked with COVID-19 (SARS-CoV-2) after five days of consecutive dosing, and dosed for seven consecutive days since the day of the challenge. The post-exposure dosing group was not dosed prior to the challenge and only dosed since the day of the challenge for seven consecutive days. As indicated below, the post-exposure vaccinated group had significantly lower viral load than the control group, which indicates that vaccination using PIKA recombinant COVID-19 vaccine can significantly inhibit virus replication and demonstrates significant therapeutic effect.

Figure 18. COVID-19 viral load in the lungs of cynomolgus monkeys 7 days after challenge



Data are shown as mean ± SEM. Significance was calculated using one-way ANOVA (*p < 0.05; ****p < 0.0001).

Phase I Clinical Trial in UAE

We completed patient enrollment of Phase I trial of PIKA recombinant COVID-19 vaccine in the United Arab Emirates with preliminary results in the first half of 2022. Phase I clinical trial is designed to evaluate the safety, tolerability and immunogenicity of PIKA recombinant COVID-19 vaccine in healthy adults. This is a Phase I, open label, dose-escalation study of three dose levels of the SARS-CoV-2 spike antigen administered intramuscularly (IM) in combination with a fixed dosage of PIKA adjuvant vaccine to evaluate the safety, tolerability, and immunogenicity of PIKA COVID-19 vaccine candidate in healthy individuals aged over 18 years. Three dose levels, namely 5 ug, 10 ug and 20 ug of recombinant spike protein with 1 mg PIKA, were administered via intramuscular injections. The study comprised of two arms. Arm A included subjects without history of COVID-19 vaccination and Arm B included subjects who will be receiving PIKA vaccine as a booster vaccination dose to those who had primary series of inactivated vaccines or mRNA vaccines. For Arm A, a total of 45 subjects were enrolled. Subjects in Group 1-3 received two doses of PIKA COVID-19 vaccine via IM administration on Days 0 and 7. For Arm B, a total of 90 subjects were enrolled and were further divided into Arm B1 (45 subjects) and Arm B2 (45 subjects). Arm B1 enrolled subjects who received COVID-19 inactivated vaccines as primary series and comprised of 15 subjects per dose (45 subjects). Arm B2 enrolled subjects who received mRNA vaccines as primary series and comprised of 15 subjects per dose (45 subjects). Subjects in Group 1-3 of Arm B1 and Arm B2 received one booster dose of PIKA COVID-19 vaccine via IM administration on Day 0. The primary endpoints included evaluation of safety as to solicited and unsolicited adverse events, serious adverse events, and adverse events of special interests; the secondary endpoints included evaluation of immunogenicity at GMTs and seroconversion rate differences of the neutralizing antibodies against the original strain and variants of concerns of SARS-CoV-2, and cell-mediated immune responses.

Figure 19

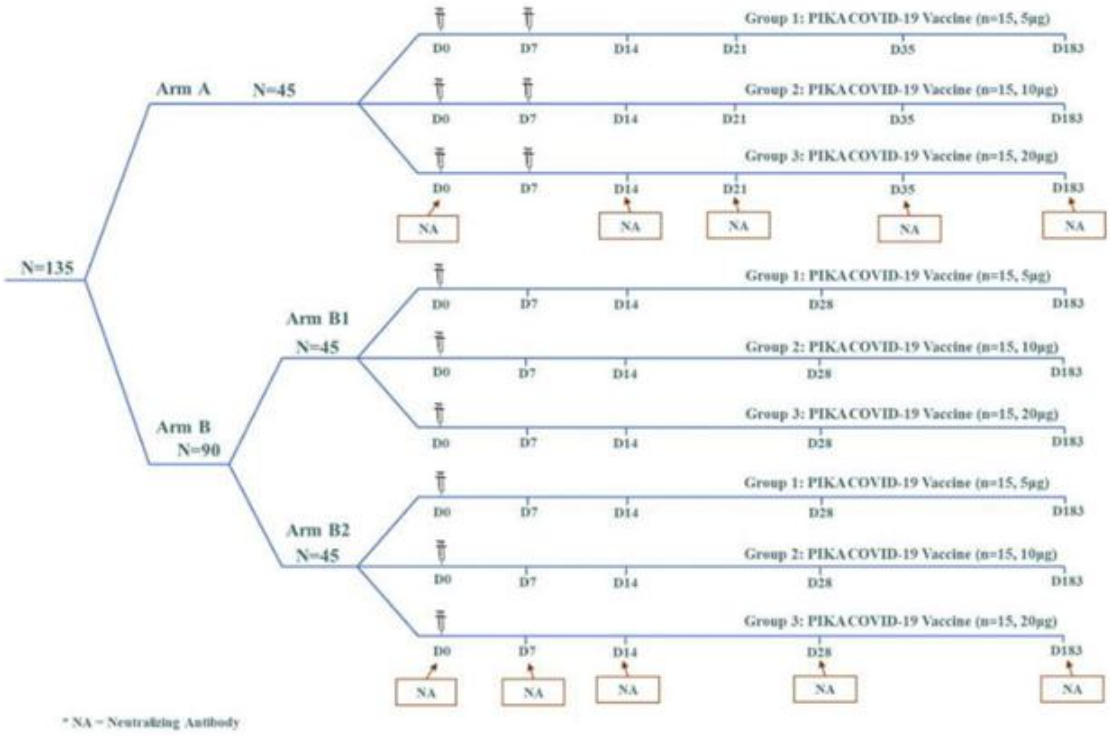
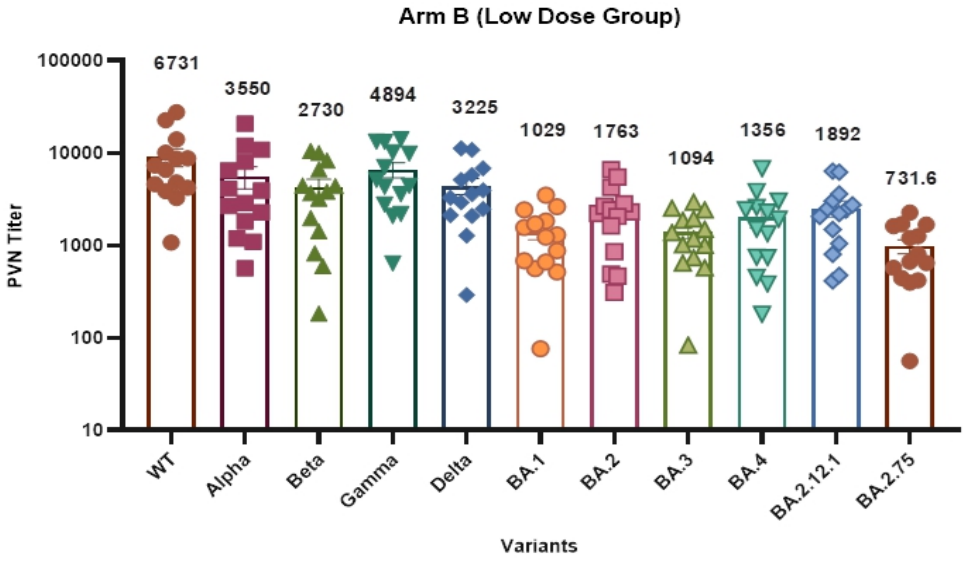


Figure 20. Schematic Diagram of Phase I Study Design

Arm	Subjects	Age	Regimen	Antigen Dosage	Sample Size
Arm A (Prime)	Subjects without history of COVID-19 vaccination	≥18 years	Two shots (Day 0,7)	5μg	15
				10μg	15
				20μg	15
Arm B (Booster)	Subjects who had completed the primary series of inactivated COVID-19 vaccination	≥18 years	One shot	5μg	15
				10μg	15
				20μg	15
	Subjects who had completed the primary	≥18 years	One shot	5μg	15
				10μg	15
	series of mRNA COVID-19 vaccination			20μg	15

The clinical trial also evaluated the neutralizing antibody titers of Arm B (low dose group) for other SARS-CoV-2 variants. Immunogenicity testing 14 days after the booster dose demonstrated that the neutralizing antibody titer against BA.2 in the serum of the subjects in the low dose group of Arm B reached 1,763 and the titer against BA.4/5 was as high as 1,356. Whereas before vaccination, the neutralizing antibody titer against BA.2 and BA.4/5 in the same groups were 31.81 and 23.5 respectively.

Figure 21. Neutralizing antibody titer of PIKA COVID-19 vaccine (5 μg/dose) 14 days post vaccination (PVNT)



Data are shown as mean ± SEM. Significance was calculated using one-way ANOVA, (vs. WT group, all other groups $p < 0.01$).

In the Phase I clinical trial, no safety concerns were revealed. No deaths and vaccine-related serious adverse events were reported. Preliminary results of Phase I study of PIKA recombinant COVID-19 vaccine showed that as basic immunization and sequential booster immunization, PIKA recombinant COVID-19 vaccines can induce the production of high-level neutralizing antibodies, which are effective for a variety of mutant strains, including Delta, Omicron sublineages BA.1, BA.2, BA.3, BA.4/5 and BA 2.12.1.

Phase II and III Clinical Trials in the UAE and Philippines

A Phase II and III, Randomized, Double-blinded Study is designed to evaluate the Efficacy, Safety and Immunogenicity of a Booster Dose of PIKA-Adjuvanted Recombinant SARS-CoV-2 Spike (S) Protein Subunit Vaccine in Adults ≥ 18 Years Old Who Received 2 or more doses of Inactivated Covid-19 Vaccine.

Primary objectives in Phase II of the study are to assess the immunogenicity of PIKA COVID-19 vaccine 14 days after the booster dose and compare to the comparator inactivated COVID-19 vaccine. It is also aimed to demonstrate the immunogenic superiority of the PIKA COVID-19 vaccine on day 7 post booster dose. In Phase III trial, the efficacy and safety of PIKA COVID-19 vaccine in comparison to that of the comparator inactivated COVID-19 vaccine will be compared.

In Phase II, a total of 300 eligible subjects were allocated in a 1:1 ratio, stratified by age group (< 60 years old vs. ≥ 60 years old) to receive PIKA COVID-19 vaccine or the comparator inactivated COVID-19 vaccine. The ratio of the GMT of neutralizing antibody on Day 14 after the booster dose of PIKA COVID-19 vaccine group and inactivated COVID-19 vaccine group will be calculated. Among 300 subjects, at least 200 were enrolled as subset of long-term immunogenicity and 100 were enrolled as subset of early immunogenicity. Among the 100 early immunogenicity subsets, the ratio of the GMT of neutralizing antibody on Day 7 after the booster dose of PIKA COVID-19 vaccine group and inactivated COVID-19 vaccine group will be calculated.

Primary objectives in Phase III of the study are to assess the efficacy and safety of PIKA COVI-19 vaccine compared to the comparator inactivated COVID-19 vaccine. The secondary objectives in Phase III study are to assess the long-term safety and immunogenicity of PIKA COVID-19 vaccine compared to the comparator inactivated COVID-19 vaccine. In phase III, total 5,656 eligible subjects were randomly allocated in a 1:1 ratio to the PIKA COVID-19 vaccine group or the inactivated COVID-19 vaccine group, stratified by age group (< 60 years old vs. ≥ 60 years old). Among total subjects, at least 6% subjects were enrolled as subset of immunogenicity. Long term safety and immunogenicity will also be evaluated.

Figure 22. Study Design and Subject Allocation

Trial Design and Subject Allocation					
Phase	**N**	**Immunogenicity Set**	**Vaccine**	**Vaccination**	**Blood Draws**
II	150	Early: 50 Long Term: 100	PIKA COVID 19	Day 0	D0, 7, 14, 90, 180, 360
	150	Early: 50 Long Term: 100	Inactivated COVID 19	Day 0	
III	5656	6% of the subjects	PIKA COVID 19	Day 0	D0, 7, 14, 360
			Inactivated COVID 19	Day 0	
Total	**5956**				

The interim data results from Phase II part of the Phase II/III head-to-head clinical study indicated PIKA COVID-19 vaccine generated a significantly higher geometric mean titers (GMTs) of neutralizing antibody against Omicron virus on both Day 7 and Day 14 after the booster dose compared with inactivated COVID-19 vaccine. In addition, similar immunogenicity superiority and statistical significance were also achieved by the measurements of GMTs of neutralizing antibody against wild type SARS-CoV-2 virus on both Day 7 and D14 after the booster dose compared with inactivated COVID-19 vaccine. These results further confirmed PIKA adjuvant's capability of accelerating human immune responses.

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.

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.

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

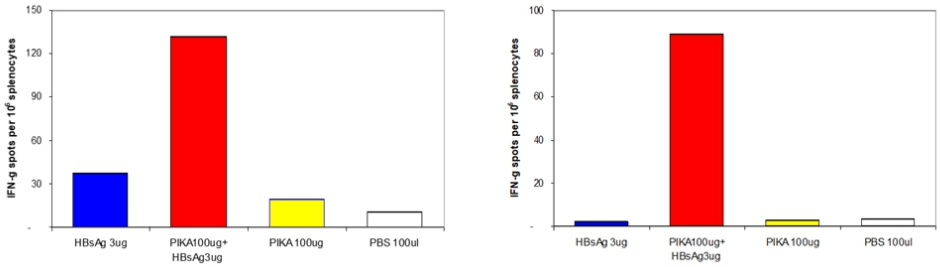
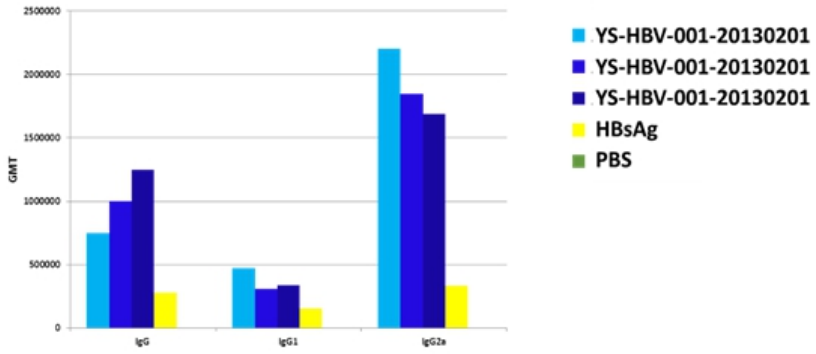


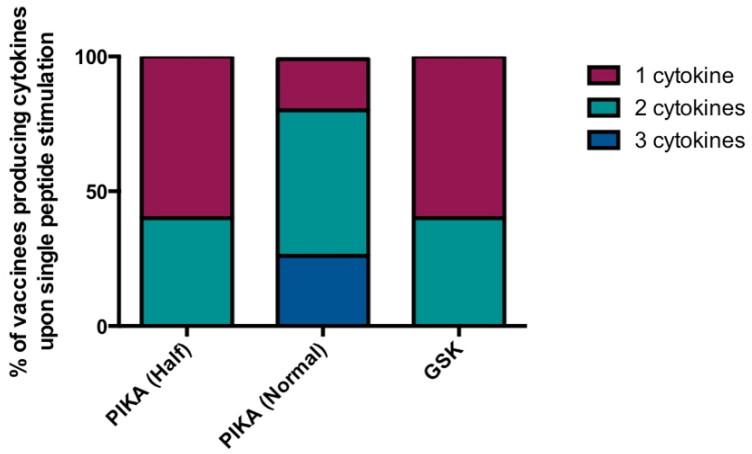
Figure 18. Anti-HBsAg antibody titers after vaccination in mice



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



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

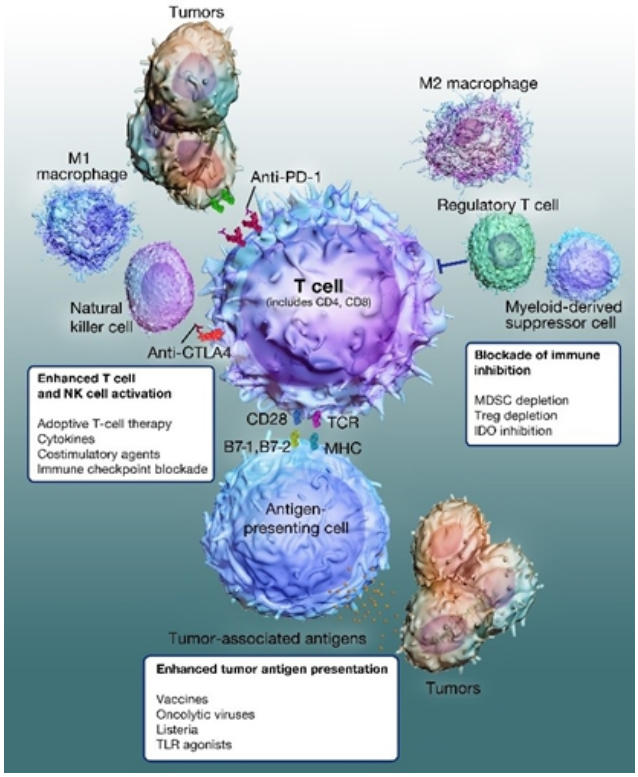
PIKA YS-ON-001 is a multiple component complex of proteins and PIKA that can reduce the immunosuppressive effect of the tumor microenvironment and enhance the anti-tumor activity of the immune system against tumor cells. We are currently independently developing PIKA YS-ON-001 as an immuno-oncology therapeutic. 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, the Company 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 cancer, lung cancer, liver cancer and melanoma subjects.

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



Anti-CTLA4: anti-cytoxic T-Lymphocyte associated protein

MHC: major histocompatibility complex

TCR: T cell receptor

TAA: Tumor-associated antigen

Anti-PD-L1: anti-programmed death ligand 1

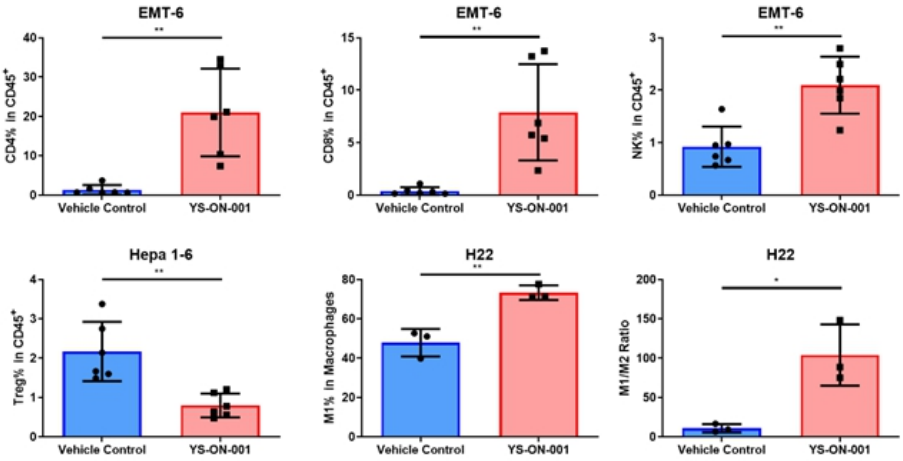
MDSC: myeloid derived suppressor cell

Treg: Regulatory T cells

M: Macrophage

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.

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



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. 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

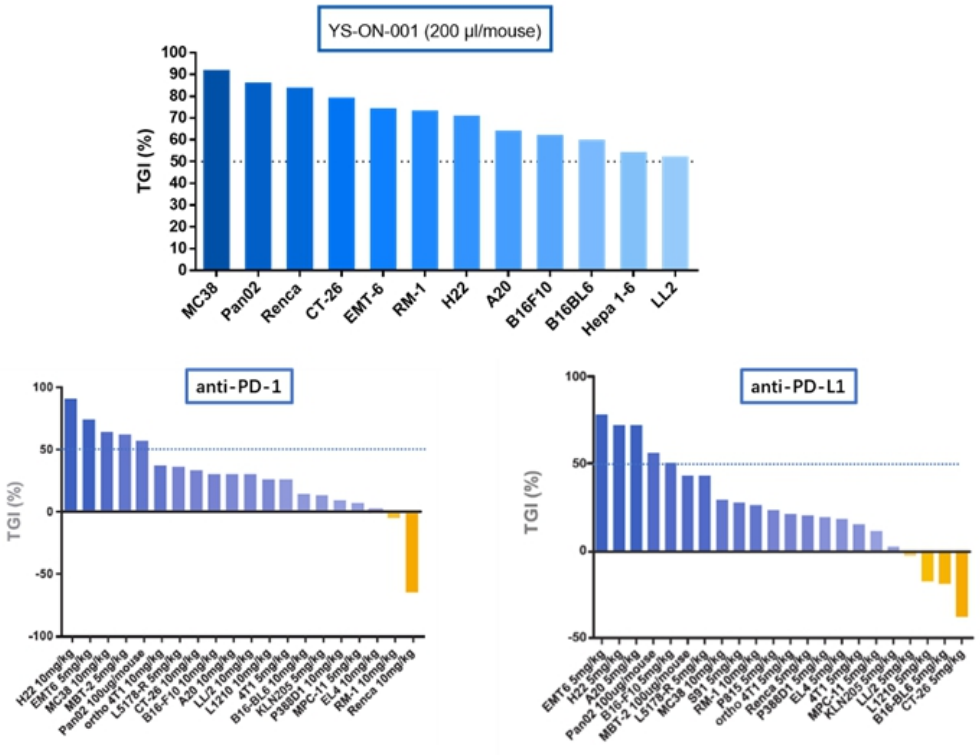
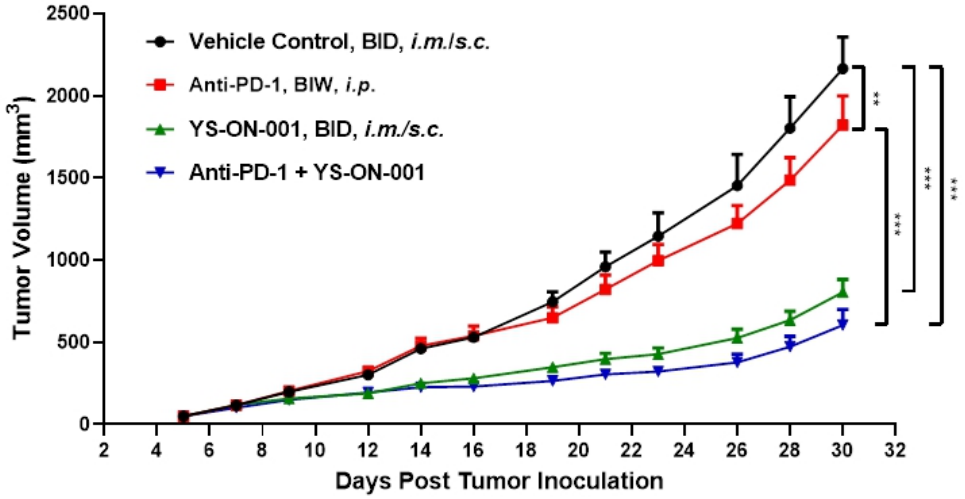


Figure 28. Enhanced anti-tumor activity of PIKA YS-ON-001 with anti-PD-1 antibody



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 multikinase inhibitor. We believe PIKA YS-ON-001 has the potential to be combined with various targeted therapies.

  (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.

  (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.

  (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.

- *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			

Phase I clinical trial

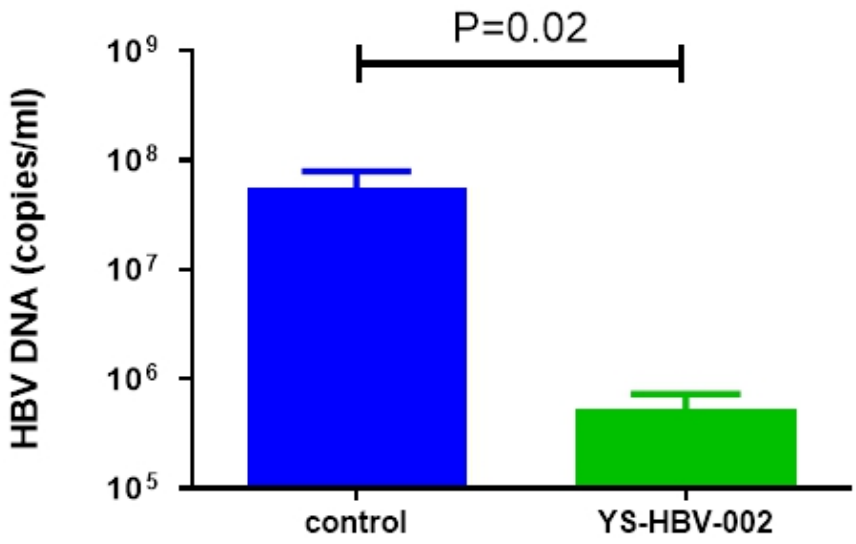
The Phase I clinical trial of PIKA YS-ON-001 is an open label, dose escalation and cohort expansion study in patients with advanced solid tumors. The objective of the Phase I clinical trial is to evaluate the safety and tolerability of YS-ON-001 in patients with advanced solid tumors who have limited 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 expect to complete Phase I clinical study in China in 2023.

Our Preclinical Stage Product Candidates

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



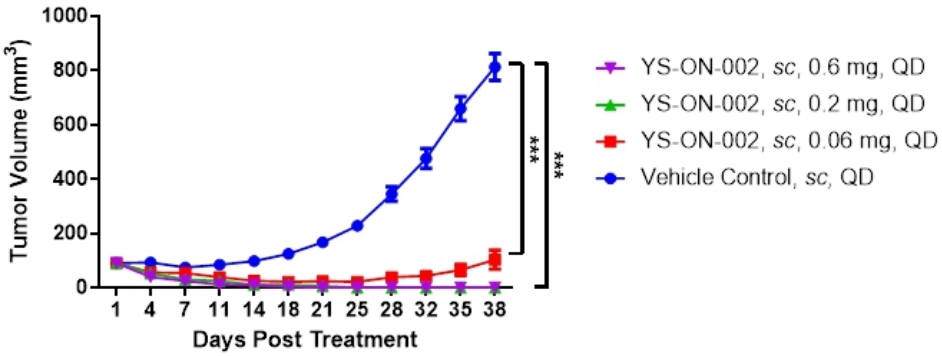
Data are shown as mean ± SEM. Significance was calculated using unpaired *t*-test.

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



Data are shown as mean ± SEM. *P*-values were analyzed with a two-way ANOVA (***$p < 0.001$)

PIKA Influenza Vaccine

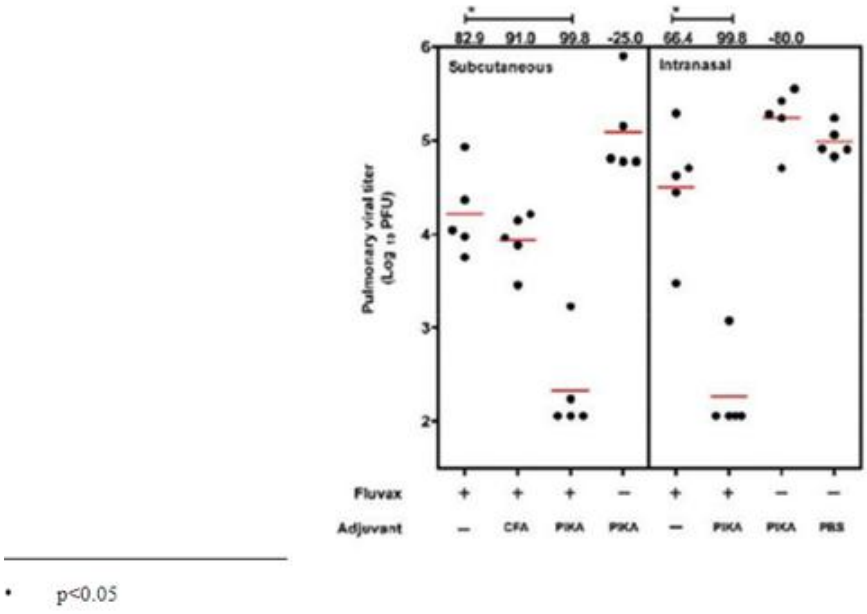
PIKA influenza vaccine is designed to contain quadrivalent seasonal inactivated influenza virus recommended by regulatory authorities regarding the annual seasonal vaccine. These inactivated influenza virus function as antigens which induce a humoral immune response, measured by hemagglutination inhibition (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.

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



* p<0.05

PIKA Rabies Vaccine (Human dipoid cell)

PIKA Rabies Vaccine (Human dipoid cell) is designed and positioned as a new generation of rabies vaccine based on our PIKA immunomodulating technology platform. Compared with PIKA Rabies Vaccine currently at clinical stage, containing PIKA agent and inactive rabies virus antigen derived from Vero cell line, the antigen component of PIKA Rabies Vaccine (Human dipoid Cell) is generated from human dipoid cell line.

By leveraging the PIKA technology, we believe that, compared to the existing rabies vaccine using human dipoid cell in the market, PIKA Rabies Vaccine (Human dipoid cell) has the potential to provide quick onset of immune response, lower dosage form and longer duration of protection and better safety advantages. We expect to move this program into IND application in 2024.

Our Strategic Collaborations

CEPI Clinical Research Collaboration

We and Coalition for Epidemic Preparedness Innovations (“CEPI”) entered into a memorandum of agreement in June 2022 in relation to our collaboration with CEPI for the clinical study of our PIKA recombinant COVID-19 vaccine where CEPI is providing technical expertise and laboratory testing support to us for such studies. CEPI is a world leading organization missioned is to promote and strengthen public-private collaboration in order to develop, manufacture and stockpile vaccines necessary to respond to emerging infectious diseases and to support vaccine research and development in connection with public health emergencies. According to the memorandum of agreement, the cooperation will last for three years. CEPI will provide us with sample testing services, including testing 900 samples for wild type virus neutralization and 180 samples for variant omicron BA.1. CEPI will pay the laboratory for the sample testing services for preclinical, phase I, phase II(a) samples from us while we will pay the laboratory for the sample testing services for phase II(b) and phase III samples, in addition to the shipping costs and customs fees. The memorandum of agreement does not affect the ownership of any IP rights in either party’s background IP. We shall exclusively own all IP of the test results and shall have the right to use it for any purposes.

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 redeemable convertible preferred stock. 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 YSJA™ 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 YSJA™ 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 YSJA™ rabies vaccines overseas. In the event of the assignment, sale, exclusive license, or other transfer of intellectual property related to YSJA™ 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 YSJA™ 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 YSJA™ rabies vaccine.

Research and Development

We believe our commitment to R&D of innovative products and technologies is fundamental to our success. We take pride in our PIKA immunomodulating technology, which has enabled a robust portfolio of product candidates. Our R&D team focuses on the key functions of the R&D process; and our scientific advisory board provide critical guidance to our R&D efforts.

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.

Since we acquired PIKA immunomodulating technology in 2010, pursued in-house advancement of the PIKA technology in multiple fronts, including the following:

- *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, COVID-19 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 four 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, (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, and (4) PIKA YS-SC2-010, also known as PIKA recombinant COVID-19 vaccine, a prophylactic and therapeutic vaccine against COVID-19 disease caused by SARS-CoV-2. 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 30 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.

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.

Scientific advisory board

Our scientific advisory board, established in 2011, plays an active role in the review of our biopharmaceutical product development programs. We also seek advice from our scientific advisory board on R&D strategy and technical matters.

Yunde Hou, M.D., Ph. D., is an academician of the Chinese Academy of Engineering and is currently the Director of the Academician Laboratory of the National Institute of Viral Disease Control and Prevention under the national CDC in China, as well as the Chief Technological Officer of National Science and Technology Major Project for Viral Diseases. He was founder and former Chairman of the Chinese Society of Virology and was one of the two laureates for the 2017 China's National Preeminent Science and Technology Award, the highest scientific award in China. Dr. Hou is also the former Dean of the Institute of Virology, the Chinese Academy of Preventive Medicine, and former Vice President of the Chinese Academy of Engineering. Dr. Hou is the leader of recombinant interferon and many genetically engineered drugs. He was the first person in China that isolated para-influenza viruses I, III and IV. He developed preventive and therapeutic licensed biological products. Dr. Hou received a B.S. in medicine from Tongji University and a Ph.D. in medical sciences from the Iwanowski Virus Research Institute of the former Soviet Union.

Mr. Yongxin Yu is an academician of the Chinese Academy of Engineering and is currently the Chief Vaccine Expert of the National Institutes for Food and Drug Control. As a leader in vaccinology and virology in China. Mr. Yu has nearly 60 years of experience in the R&D of vaccines and has been widely recognized for his contributions to the quality control and research of vaccines for diseases such as Japanese encephalitis and rabies. From the 1950s to the 1980s, he led the development of the SA14-14-2 strain for the Japanese encephalitis live attenuated vaccine, which was the first live attenuated vaccine against Japanese encephalitis in the world and has fundamentally suppressed the viral spread in China since its mass adoption. He also chaired the strain selection and cultivation relating to primary hamster kidney cell rabies vaccine in China, which improved the safety and efficacy profile compared with previous rabies vaccine then available in China. Mr. Yu has authored or co-authored numerous articles and books and currently serves on the editorial boards of several peer-reviewed journals.

Mann Fung, M.D. is the chief executive officer of Tavotek Biotherapeutics, a biopharmaceutical company focused on medicines for cancers and autoimmune diseases. He was a former Vice President of Johnson & Johnson, where he led the development and strategies on innovative oncology therapies in the Asia-Pacific region. Prior to that, he served as Vice President for the R&D of innovative antitumor drugs and 36 mmune-oncology therapeutics at the U.S. headquarters of Johnson & Johnson, during which he was noted for leading the development of Ibrutinib, an internationally recognized potent inhibitor of Bruton's tyrosine kinase. Dr. Fung also served at several positions at Eli Lilly and Company, including as Head of Oncology and Critical Care Products for Lilly Japan. Dr. Fung is a fellow of American College of Physicians and also a scientific advisory board member of Virogin Biotech. Dr. Fung obtained his M.D. degrees from the University of Utah. He also obtained a master's degree in health care management from Harvard University.

Guang Gao, Ph.D. is the senior technical officer at Shanghai Representative Office of PATH, an international non-profit organization to develop and deliver lifesaving vaccines to women, children, and communities around the globe. Dr. Gao has distinguished expertise in advising PATH partners in China and working with vaccine manufacturers in China to improve their quality system and manufacturing capability to bring their products to domestic and global markets. She has extensive experience in the fields of GMP manufacturing regulation, regulatory inspection, review and approval of vaccines and biological products in China and the United States. During her tenure at the FDA China office, she provided authoritative guidance and consultations regarding regulatory inspections and investigations and worked directly with the Chinese government for public health system evaluations. Prior to that, Dr. Gao served multiple positions at the Center for Biologics Evaluation and Research of the FDA, including as a national authoritative regulatory review scientist to provide technical leadership and guidance for regulatory activities. Dr. Gao has obtained the Regulatory Affairs Certification accredited by the Regulatory Affairs Certification Board and the Certified Quality Auditor Certification accredited by the American Society for Quality. Dr. Gao also published numerous papers on peer-reviewed scientific journals. Dr. Gao received her Ph.D. degree in biochemistry from Nanjing University.

Research and development team and activities

In-house research and development team and activities

As we engaged in both the manufacturing of YSJA™ 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 221 employees or 28.59% of our total employees as of March 31, 2023. Our R&D team is located in Beijing, Shenyang (China), Maryland (the United States) and Singapore, 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.

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 four R&D sites located in Maryland (the United States), Singapore, 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."

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 Yisheng is the proprietary owner of a vast majority of our patents owning about 70 patents in over 30 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
PIKA adjuvant	Polyinosinic acid-polycytidylic acid-based adjuvant	Singapore Yisheng	Australia, Brazil, Canada, Cuba, the European Union, Austria, Belgium, Switzerland, Denmark, France, the United Kingdom, Ireland, Italy, Netherlands, Poland, Turkey, Spain, Sweden, Germany, Indonesia, Israel, India, South Korea, Malaysia, New Zealand, the Philippines, Russia, Singapore, Thailand, Taiwan (China), the United States, Vietnam, South Africa the United States, Mexico	Granted	2025 to 2027	Composition of matter
		Singapore Yisheng	The United States, Mexico	Granted	2025	
	Immunogenic substances comprising a polyinosinic acid-polycytidilic acid-based adjuvant	Singapore Yisheng	China, Australia, Cuba, Indonesia, India, Mexico, Malaysia, New Zealand, the Philippines, Russia, Singapore, Taiwan (China), the United States, Vietnam, South Africa	Granted	2026 to 2028	Composition of matter
	Mucosal Immunogenic substances comprising a polyinosinic acid-polycytidilic acid-based adjuvant	Singapore Yisheng	Australia, Canada, Cuba, Indonesia, South Korea, Malaysia, New Zealand, the Philippines, Singapore, South Africa	Granted	2026 to 2028	Composition of matter
		Beijing Yisheng	China	Granted	2026	
		Singapore Yisheng	Taiwan (China)	Granted	2027	
	Method for reducing DNA impurities in viral compositions	Singapore Yisheng	The European Union, Switzerland, France, United Kingdom, Germany, Singapore, the United States	Granted	2030	Process/Method
		Beijing Yisheng	China	Granted	2030	
PIKA HBV	A composition for treating and/or preventing Hepatitis B virus infection	Singapore Yisheng	Indonesia, the United States, the United States (continuation)	Granted	2038	Composition of matter
		Singapore Yisheng	Australia, Canada, Brazil, Hong Kong, Cuba, the European Union, India, South Korea, Mexico, Malaysia, New Zealand, the Philippines, Russia, Singapore, Thailand, Vietnam, China, South Africa	Pending	N/A	
PIKA rabies vaccine (Vero cell)	A composition comprising PIKA adjuvant	Singapore Yisheng	China, Indonesia, India, Russia, the Philippines, South Africa	Granted	2034 to 2037	Composition of matter
		Singapore Yisheng	Brazil, Thailand, the United States, Vietnam	Pending	N/A	
PIKA YS-ON-001 (Cancer)	A composition comprising PIC for treatment of cancer	Singapore Yisheng	Australia, the United States, the European Union, Indonesia, India, South Korea, Mexico, Russia, Singapore, South Africa	Granted	2037 to 2038	Composition of matter
		Singapore Yisheng	China, Brazil, Canada, Hong Kong, Cuba, Malaysia, New Zealand, the Philippines, Thailand, the United States(continuation), Vietnam	Pending	N/A	

	Method for adapting influenza viruses to vero cell	Singapore Yisheng	the United States	Granted	2038	Method/Process
		Singapore Yisheng	Singapore, the United States (continuation), China, the European Union	Pending	N/A	
PIKA YS-ON-001	A cancer tumor treatment medication and its application in the preparation of medication for treating cancer tumor	Beijing Yisheng	China	Granted	2025	Composition
PIKA COVID-19	Composition containing polynucleotide and its application in preventing or treating COVID-19	Beijing Yisheng & Liaoning Yisheng	South Africa	Granted	2042	
			China, the United States, New Zealand, Singapore, the United Arab Emirates	Pending	N/A	

(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.”

Trademarks and domain names

As of the date of this Annual Report, we own 18 registered trademarks in China. We have three registered domain names, namely liaoningyisheng.com, yishengbio.com and ysbiopharm.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, 2023 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 YSJA™ 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.

In November 2022, our manufacturing facilities for PIKA recombinant COVID-19 vaccine product passed an audit by a European Union Qualified Person (QP). The audit was based on the guidance of European Union Good Manufacturing Practice ("EU GMP") and the guiding principles of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This EU QP audit involved a comprehensive and in-depth audit focused on the production quality of PIKA recombinant COVID-19 vaccine. The audit covered production systems, facility and equipment management, quality control, quality assurance, material management and other systems. This indicates our manufacturing site complies with European pharmaceutical GMP standards and has the ability to provide high quality pharmaceutical product for clinical studies and commercialization in European and international markets.

Our current manufacturing facilities, certified under China 2010 GMP standard, have an annual production capacity of approximately 15 million doses of YSJA™ rabies vaccine. In the three fiscal years ended March 31, 2023, we manufactured approximately 26.5 million doses of YSJA™ rabies vaccine. Since the GMP certified plant started production in February 2020, the utilization has increased gradually and reached 58.33%, 81.25% and 100%, for the three fiscal years ended March 31, 2023 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 YSJA™ 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.

Expansion plan

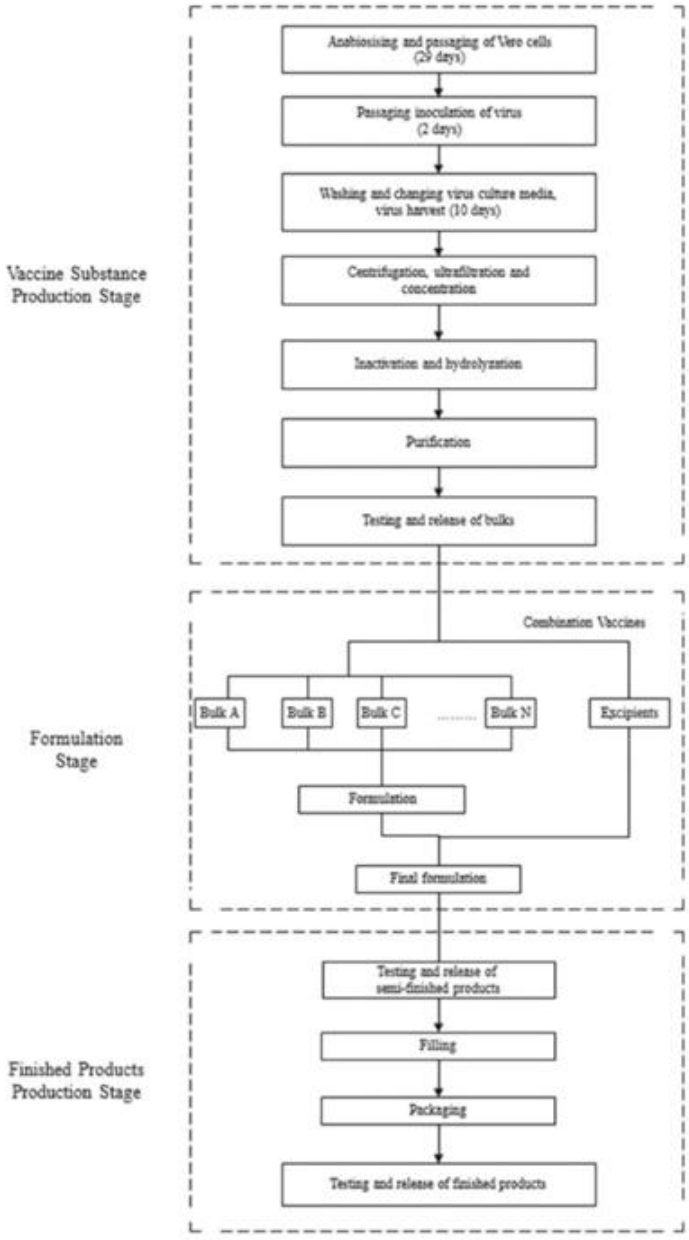
We own the land use right to three adjacent parcels of land located in Shenyang Economy and Technology Development Zone, Shenyang, China with an aggregate site area of 215,357 sq.m. To facilitate the R&D efforts and the potential product launches, we plan to establish new manufacturing workshops in China 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 recombinant COVID-19 vaccine in Shenyang (China)	6,831	March 2021	By the end of 2023	500 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 YSJA™ rabies vaccine.



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 YSJA™ rabies vaccine is approximately five months, and the shelf life of YSJA™ 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, 2023 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.

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 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.

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, 2023.

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 YSJA™ 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.

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 YSJA™ 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, 2023, 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.

As of the date of this Annual Report, we have a dedicated in-house commercialization team of approximately 50 employees, with an average industry experience of over 12 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 YSJA^{TM} 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 YSJA^{TM} 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, 2023, we engaged over 129 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.

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, 2023, through which we delivered our vaccines to county-level CDCs.

Customers

We started the sales of YSJA^{TM} 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. In addition, we perform periodical reviews of our suppliers and facilities in accordance with GMP requirements.

Purchases from our top five suppliers accounted for 59.6%, 44.7% and 66.9% of our total purchases in the fiscal years ended March 31, 2021, 2022 and 2023, respectively, and purchases from our largest supplier accounted for 37.9%, 20.9% and 37.9% 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 PIKA rabies vaccine, PIKA Recombinant COVID-19 vaccine, YS-HBV-002 and YS-ON-002.

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:

- *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.

- *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 YSJA™ 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.

Licenses, Permits and Approvals

As of the date of this Annual Report, we have obtained all requisite 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
YSJA™ rabies vaccine	Drug Re-registration Certificate	Liaoning Yisheng	Medical Products Administration of Liaoning Province	July 13, 2020 - July 12, 2025
YSJA™ rabies vaccine/PIKA Recombinant COVID-19 vaccine	Drug Manufacturing License	Liaoning Yisheng	Medical Products Administration of Liaoning Province	June 15, 2022 - August 14, 2024

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 YSJA™ 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, 2023 and up to the date of this Annual Report, 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.

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.

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.

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.

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.

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 lastly 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 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 and effective July 1, 2019, 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 Administrative Department of Science and Technology under the State Council is responsible for the management of human genetic resources at the national level, and the administrative departments of science and technology under the provincial governments are responsible for the management of human genetic resources at local level and are vertically directed by the central government of the PRC. 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 and a drug approval number, assuming the applicant has a valid Drug Manufacturing License and the requisite production conditions for the new medicine have been met. All pharmaceutical products produced in China must bear drug approval numbers issued by the NMPA, with the exception of certain Chinese herbs and Chinese herbal medicines in soluble form. Drug manufacturing enterprises must obtain drug approval numbers before manufacturing any drug. A drug approval number issued by the NMPA is valid for five years and the applicant shall apply for renewal six months prior to its expiration date. Application for drug registration includes application for new drugs, application for generic drugs, application for imported drugs, application for supplementary drugs and its re-registration application. A new drug application refers to an application for registration of a drug that has not yet been marketed for sale in China. In addition, the registration of drugs that change the dosage form of the marketed drugs, change the route of administration, and increase the new indications shall be reported in accordance with the application procedures for new drugs. The NMPA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE. According to the Drug Registration Provisions, drug registration is regulated according to Chinese medicine, chemical medicine and biological products. As compared to the current effective version, 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.

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 provide 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.

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 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 Standing Committee of the National People's Congress (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.

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.

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 adopts 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.

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.

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, the GMP Certificate 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.

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 Standing Committee of the NPC 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.

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 NPC 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 NPC on August 20, 2021 and took effect 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.

Anti-bribery

According to the Anti-Unfair Competition Law of the PRC (the "Anti-Unfair Competition Law"), which was passed by the SCNPC September 2, 1993, became effective on December 1, 1993 and was last amended on April 23, 2019, 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 conducts bribe, the regulatory authorities shall confiscate its illegal income and impose a fine ranging from RMB100,000 to RMB3,000,000. Severe violations shall have their business licenses revoked.

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 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. A pharmaceutical company will not be penalized by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third-party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third-party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third-party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of its failure to monitor their operating activities.

According to the Criminal Law of the PRC, which was last amended December 26, 2020 and became effective on March 1, 2021, 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 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 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 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 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.

Regulations relating to product liability

Pursuant to the Product Quality Law of the PRC promulgated on February 22, 1993 and latest amended 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 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 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 (2021 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 January 1, 2022, sets out special administrative measures in respect of the access of foreign investments in a centralized manner, and the Encouraging List which 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 lasted amended on October 26, 2018. 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 promulgated by the SCNPC 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.

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 October on 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.

Social securities

According to the Social Insurance Law of PRC, issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was 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 amended by the Standing Committee of the NPC 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 and amended on September 4, 1992, August 25, 2000, December 27, 2008 and came into effect on October 1, 2009 and the Implementing Rules of the Patent Law of the PRC, promulgated by the China Patent Bureau Council on January 19, 1985, and amended on January 9, 2010 and came into effect on February 1, 2010, the term "invention-creations" refers to inventions, utility models and designs. The duration of a patent right for inventions shall be 20 years and the duration of a patent right for utility models and designs shall be ten years, both commencing from the filing date. In the event a dispute arises due to a patent being exploited without the prior authorization of the patentee, that is to say an infringement upon the patent right of the patentee. In addition, pursuant to the Patent Law of the PRC which was released on October 17, 2020 and came into effect on June 1, 2021, the duration of a patent right for designs shall be 15 years, all commencing from the application date.

Trademarks

Pursuant to the Trademark Law of the PRC promulgated on August 23, 1982 and amended on April 23, 2019 and came into effect on November 1, 2019, the Implementation Regulations of the Trademark Law of PRC issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC (the "Trademark Office") shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for 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.

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). 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 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 which 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.

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 and five supporting guidelines, which came into effect on March 31, 2023.

The Trial Administrative Measures for Overseas Listing 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 (v) 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 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. 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 Trial Administrative Measures for Overseas Listing 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 Trial Administrative Measures for Overseas Listing, 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.

Regulations relating to taxation

Enterprise income tax

The Enterprise Income Tax Law of the PRC (the "EIT Law"), promulgated by the NPC March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law, or the Implementation Rules, promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, 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, came into effect 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%.

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.

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:

(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;

(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;

(3) not to make substantial amendments to the trial except with approval of HSA;

(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;

(5) to ensure that information in the investigator's brochure for the trial is concise, objective and kept up to date;

(6) to ensure the clinical trial is conducted under supervision of qualified private investigator;

(7) to ensure the clinical trial is only conducted at the specified trial site;

(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;

(9) to put and keep in place arrangements to ensure compliance with principles of GCP;

(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;

(11) to keep record of clinical trials;

(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

(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.

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.

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:

(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;

(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;

(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;

(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;

(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

(6) protection obligation — an organization must implement reasonable security arrangements for the protection of personal data in its possession or under its control;

(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;

(8) transfer limitation obligation — personal data must not be transferred out of Singapore except in accordance with the requirements prescribed under the PDPA; and

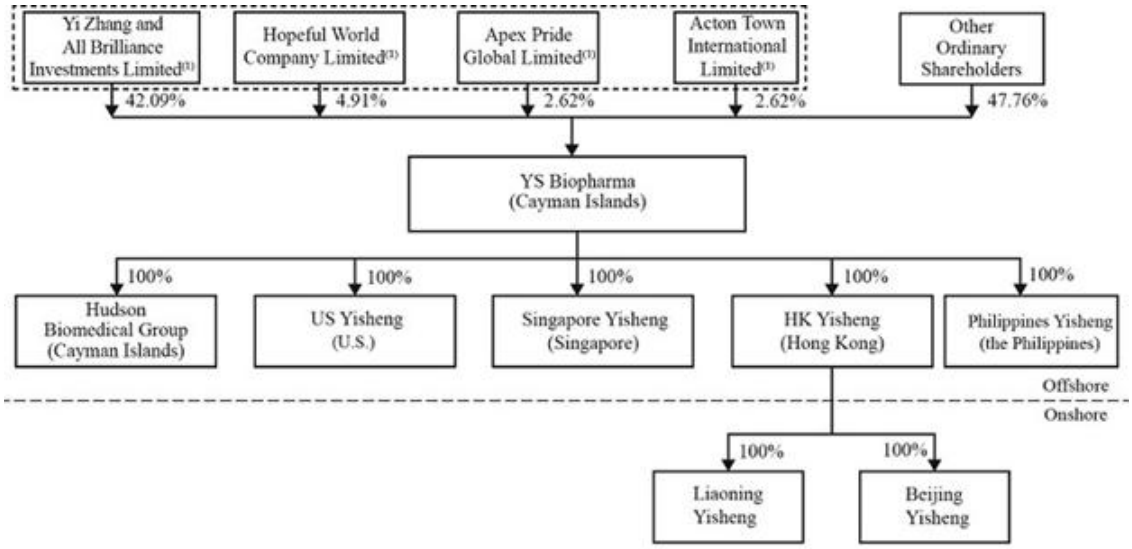
(9) openness obligation — an organization must implement the necessary policies and procedures in order to meet the obligations under the PDPA and shall make information about its policies and procedures publicly available.

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.

C. Organizational Structure

We were incorporated under the laws of Cayman Islands as an exempted company with limited liability in November 2020. Our history can be traced back to 2002 when Mr. Yi Zhang, our founder and controlling shareholder, started the vaccine business in the PRC, and has expanded our international business operation in the United States and Singapore since 2009.

The following diagram illustrates our corporate structure as of the date of this Annual Report.



(1) (i) Mr. Yi Zhang and the entities controlled by Mr. Yi Zhang, including An Diang Group Holdings Limited, YXRT Company Limited and All Brilliance Investments Limited; (ii) Ms. Rui Mi and the entities controlled by Ms. Rui Mi, including Honeydrew Flower Field Ltd., ZM Home Limited and Hopeful World Company Limited; (iii) Ms. Xu Zhang and the entities controlled by Ms. Xu Zhang, including Apex Pride Global Limited, Prosperous Sunrise Company Limited and Much Galaxy Company Limited; and (iv) Ms. Nan Zhang and the entities controlled by Ms. Nan Zhang, including Spring Nanmu Islands Ltd., NNZF Company Limited and Acton Town International Limited (the "Concert Parties") entered into the Concert Party Agreement, pursuant to which, the concert parties agree and acknowledge that they have voted since commencement of our business, and will continue to vote, themselves or through any entity directly or indirectly controlled by them that own our equity interest, unanimously for any resolutions proposed at our board meetings and/or shareholders meeting, where applicable. According to the Concert Party Agreement, if the Concert Parties are unable to reach unanimous consensus, Yi Zhang is entitled to determine how to vote for and on behalf of himself and the Concert Parties. The Concert Agreement remains effective unless otherwise terminated by mutual consent of the Concert Parties.

D. Property, Plants and Equipment

Owned properties

As of March 31, 2023, we owned and operated one business facility in Shenyang, China primarily for manufacturing purposes. We have built two manufacturing workshops for YSJA™ rabies vaccine, which are located in the Shenyang Economy and Technology Development Zone, Shenyang, China. We have 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 sq.m, which will expire in January 2060, (2) a right of land use for 73,724 sq.m, which will expire in January 2060, and (3) a right of land use for 96,978 sq.m, which will expire in December 2056.

Leased properties

As of March 31, 2023, we operated our business through four leased properties in Beijing, the United States and Singapore. Such properties primarily serve as offices. The expiration dates of two leased properties in Beijing, the leased properties in United and Singapore are November 2022, September 2025, November and March 2025, respectively. We plan to renew our leases or negotiate new terms when the existing leases expire.

As of March 31, 2023, our leased property in Beijing with a total gross floor area of 5,047 sq.m. 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.

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 significant revenue and growth potential. We take pride in our marketed vaccine product, YSJA™ rabies vaccine, which was the first aluminum-free lyophilized rabies vaccine launched in China. As of the date of this report, approximately 98 million doses of YSJA™ rabies vaccine have been administered for post-exposure protection against rabies. With our track record of commercialization, YSJA™ rabies vaccine were achieved high production scalability and wide market recognition. Since we commenced the sales of YSJA™ rabies vaccine in October 2020 and up to March 31, 2023, we sold more than 19.9 million doses to 1,687 county-level CDCs in China.

In addition to the commercialized YSJA™ 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 Annual Report, we have a portfolio of eight innovative product candidates: (1) four product candidates under various clinical development stages, including PIKA rabies vaccine, PIKA recombinant COVID-19 vaccine, PIKA YS-ON-001 and PIKA YS-HBV-001, and (2) four preclinical stage product candidates, targeting HBV, rabies, influenza, rabies and cancer with enormous medical demand. In addition, we are working on a series of therapeutic targets and products at the discovery stage. We have been granted about 70 patents across more than 30 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, 2023, we had an accumulated deficit of $272.7 million. We have funded our operations primarily with proceeds from revenues generated from the sales of our marketed product, YSJA™ rabies vaccine, borrowings under our loan facilities, and private placements of our shares.

Response to COVID-19

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. 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. See "Item 3. Key Information—D. Risk Factors—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."

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.

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.

Our ability to increase the sales of our marketed product

We commenced the production of our marketed product, YSJA™ rabies vaccine with our GMP-compliant manufacturing facilities in February 2020 and the sales and marketing in October 2020. Since October 2020 and up to March 31, 2023, we had sold approximately 19.9 million doses of product to 1,687 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 significant unmet demand for rabies vaccine in China and Southeast Asia. We plan to expand our manufacturing facilities by establishing manufacturing facilities in Shenyang (China) and enhance our sales efforts by expanding our commercialization team, marketing service providers and county-level CDC coverage.

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, hawse have developed a robust pipeline of product candwhether we are able to effectively idates targeting viral infections and cancer, including four clinical stage candidates and four preclinical candidates. We expect PIKA rabies vaccine to lead and expedite our progress in the development and commercialization of existing pipeline products. We believe that our accumulated experience and resources in vaccine sales, manufacture and commercialization will be a strong driving force for the market launch of PIKA rabies vaccine and lay a solid foundation for our 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 significantly affected by our costs and expenses. During the two fiscal years ended March 31, 2023, our results of operations were significantly affected by our R&D expenses, administrative expenses, selling expenses 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 R&D expenses and administrative expenses, among others, will continue to have a significant impact on our financial performance.

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 have devoted significant resources to R&D activities. For the fiscal years ended March 31, 2023, 2022 and 2021, our R&D expenses were RMB318.7 million ($46.4 million), RMB211.2 million, and RMB94.4 million, respectively. Our current R&D activities primarily relate to the clinical advancement of our product candidates. 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.

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.

As we began the sales and marketing of our marketed product in October 2020 and has a pipeline of product candidates from preclinical to late-stage, we intend to leverage our in-house commercialization team and external service providers to expand our sales network and anticipate that our selling expenses will increase in the future to support the implementation of our sales plan.

We expect our cost structure to evolve as we continue to develop and expand our business. As the clinical trials of our product candidates continue to progress and as we gradually bring our product pipeline to 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 cost primarily consists 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 rising.

Operating expenses

Selling and Marketing Expenses

Selling and marketing expenses primarily consisted of employee benefits expenses, travel and entertainment expenses, 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 represented such expenses 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.

General and administrative expenses

General and administrative expenses primarily consisted of employee benefits expenses, depreciation and amortization, allowance 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 expenses for property, plant and equipment and right-of-use assets and amortization expenses for intangible assets used for administrative purpose.

Research and development expenses

R&D expenses primarily consisted of employee benefits expenses, testing and clinical trial expenses, consulting service fees, depreciation and amortization, office and leasing expenses 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, YS Biopharma is not subject to tax on income or capital gains. In addition, upon payments of dividends by YS Biopharma to our shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong. Under the Hong Kong tax laws, Yisheng Hong Kong 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 December 2021, 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. Beijing Yisheng is subject to corporate income tax at a statutory rate of 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% during the reported fiscal periods.

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			2022		Variance	
	RMB	US$	%	RMB	%	RMB	%
Revenues	687,201,070	100,004,521	100.0	502,949,894	100.0	184,251,176	36.6
Cost of revenues	153,360,262	22,317,660	22.3	117,066,090	23.3	36,294,172	31.0
Gross profit	533,840,808	77,686,861	77.7	385,883,804	76.7	147,957,004	38.3
Operating expenses:							
Selling and marketing	272,927,356	39,717,589	39.7	185,999,704	37.0	86,927,652	46.7
General and administrative	81,595,277	11,874,103	11.9	107,620,500	21.4	(26,025,223)	(24.2)
Research and development	318,700,526	46,378,702	46.4	211,222,263	42.0	107,478,263	50.9
Total operating expenses	**673,223,159**	**97,970,394**	**98.0**	**504,842,467**	**100.4**	**168,380,692**	**33.4**
Loss from operations	**(139,382,351)**	**(20,283,533)**	**(20.3)**	**(118,958,663)**	**(23.7)**	**(20,423,688)**	**17.2**
Other income (expenses):							
Late fees related to income tax	(3,603)	(524)	0.0	(231,231)	0.0	227,628	(98.4)
Late fees related to social security insurance	(747,609)	(108,795)	(0.1)	(1,852,378)	(0.4)	1,104,769	(59.6)
Government grants	26,072,517	3,794,187	3.8	23,020,413	4.6	3,052,104	13.3
Financial expenses, net	(30,857,673)	(4,490,544)	(4.5)	(2,717,433)	(0.5)	(28,140,240)	1,035.5
Fair value changes of warrant liability	21,358	3,108	0.0	-	0.0	21,358	100.0
Other income (expense), net	551,760	80,295	0.1	(327,987)	(0.1)	879,747	268.2
Total other income (expense), net	**(4,963,250)**	**(722,273)**	**(0.7)**	**17,891,384**	**3.6**	**(22,854,634)**	**127.7**
Loss before income taxes	**(144,345,601)**	**(21,005,806)**	**(21.0)**	**(101,067,279)**	**(20.1)**	**(43,278,322)**	**42.8**
Provision for income taxes	**(1,133,504)**	**(164,952)**	**(0.2)**	**(4,937,122)**	**(1.0)**	**3,803,618**	**(77.0)**
Net Loss	**(145,479,105)**	**(21,170,758)**	**(21.2)**	**(106,004,401)**	**(21.1)**	**(39,474,704)**	**37.2**

	Fiscal Years Ended March 31,					
	2022		2021		Variance	
	RMB	%	RMB	%	RMB	%
Revenues	502,949,894	100.0	257,015,929	100.0	245,933,965	95.7
Cost of revenues	117,066,090	23.3	59,656,877	23.2	57,409,213	96.2
Gross profit	385,883,804	76.7	197,359,052	76.8	188,524,752	95.5
Operating expenses:						
Selling and marketing	185,999,704	37.0	73,485,259	28.6	112,514,445	153.1
General and administrative	107,620,500	21.4	155,334,386	60.4	(47,713,886)	(30.7)
Research and development	211,222,263	42.0	94,387,144	36.7	116,835,119	123.8
Total operating expenses	**504,842,467**	**100.4**	**323,206,789**	**125.7**	**181,635,678**	**56.2**
Loss from operations	**(118,958,663)**	**(23.7)**	**(125,847,737)**	**(48.9)**	**6,889,074**	**(5.5)**
Other income (expenses):						
Late fees related to income tax	—	—	(11,464,741)	(4.5)	11,464,741	(100.0)
Late fees related to tax other than income tax	(231,231)	0.0	(7,261,947)	(2.8)	7,030,716	(96.8)
Late fees related to social insurance	(1,852,378)	(0.4)	(7,701,793)	(3.0)	5,849,415	(75.9)
Government grants	23,020,413	4.6	3,530,405	1.4	19,490,008	552.1
Financial expense, net	(2,717,433)	(0.5)	(29,689,927)	(11.6)	26,972,494	(90.8)
Other income, net	(327,987)	(0.1)	4,063,743	1.6	(4,391,730)	(108.1)
Total other income (expense), net	**17,891,384**	**3.6**	**(48,524,260)**	**(18.9)**	**66,415,644**	**(136.9)**
Loss before income taxes	**(101,067,279)**	**(20.1)**	**(174,371,997)**	**(67.8)**	**73,304,718**	**(42.0)**
Provision for income taxes	(4,937,122)	(1.0)	(17,454,245)	(6.8)	12,517,123	(71.7)
Net loss	**(106,004,401)**	**(21.1)**	**(191,826,242)**	**(74.6)**	**85,821,841**	**(44.7)**

Fiscal year ended March 31, 2023 compared to fiscal year ended March 31, 2022.

Revenue

Our revenue increased by 36.6% from RMB502.9 million for the fiscal year ended March 31, 2022 to RMB687.2 million ($100.0 million) for the fiscal year ended March 31, 2023, primarily because (1) the sales volume increased due to the expansion of CDC and hospital access resulting from the professional promotion and doctors' recognition; and (2) the product price increased by approximately RMB2 per dose.

Cost of revenue

Our cost of revenue primarily consisted of raw material costs, staff costs, manufacturing costs and depreciation expenses. The cost increased by 31.0% from RMB117. 1 million for the fiscal year ended March 31, 2022 to RMB153.4 million ($22.3 million) for the fiscal year ended March 31, 2023. The increase in costs was attributable primarily to the increase in sales volume of YSJA™ rabies vaccine products.

Gross profit and gross margin

Our gross profit increased by 38.3% from RMB385.9 million for the fiscal year ended March 31, 2022 to RMB533.8 million ($77.7 million) for the fiscal year ended March 31, 2023. The increase in gross profit was primarily due to the increase in revenue and unit price. Our gross margin remained relatively stable for the fiscal years ended March 31, 2023 and 2022.

Selling expenses

Selling expenses increased by 46.7% from RMB186.0 million for the fiscal year ended March 31, 2022 to RMB272.9 million ($39.7 million) for the fiscal year ended March 31, 2023. The increase in selling expenses was primarily due to (1) an increase of RMB1.1 million in employee benefits, and (2) an increase of RMB86.9 million in promoting and marketing service fees in order to expand the access to district and county CDCs and hospitals.

The following table sets forth a breakdown of our selling expenses in absolute amount and as a percentage of the total selling expenses for the periods indicated.

	Fiscal Years Ended March 31					
	2023		2022		Variance	
	RMB	%	RMB	%	RMB	%
Promoting and marketing service fees	249,347,280	91.4	162,461,330	87.3	86,885,950	53.5
Employee benefits	21,369,530	7.8	20,283,326	10.9	1,086,204	5.4
Other	2,210,546	0.8	3,255,048	1.8	(1,044,502)	(32.1)
Total	**272,927,356**	**100.0**	**185,999,704**	**100.0**	**86,927,652**	**46.7**

General and administrative expenses

General and administrative expenses decreased by 24.2% from RMB107.6 million for the fiscal year ended March 31, 2022 to RMB81.6 million ($11.9 million) for the fiscal year ended March 31, 2023, primarily because (1) the professional service fee decreased significantly by RMB29.4 million, of which RMB32.8 million offering cost was capitalized; and (2) allowance for obsolete inventories decreased by RMB4.7 million, partially offset by an increase of RMB3.6 million in provision for trade receivables.

Our bad debt expenses were RMB10.8 million for the fiscal year ended March 31, 2023, representing an increase of RMB5.7 million or 111.4% from RMB5.1 million for 2022. Bad debt expenses 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.

From April 1, 2023 to July 26, 2023, being the date of the auditors' opinion on our financial statement for the two fiscal years ended March 31, 2023, the subsequent settlement of our accounts receivable as of March 31, 2023 is shown in the following table:

Fiscal Year Ended March 31,	0-90 days	90-180 days	180-365 days	>365 days	Total
2023(RMB)	25,828,981	60,212,761	78,120,813	16,717,979	180,880,534
2023(US)	3,758,747	8,762,426	11,368,484	2,432,874	26,322,531

As of July 26, 2023, we had collected approximately RMB181 million, or 37%, of our accounts receivable as of March 31, 2023. We are not aware of any collection risk on the remaining balance.

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 25 days, or 10.7%, from 234 days for the fiscal year ended March 31, 2022 to 259 days for the fiscal year ended March 31, 2023. The increase in days sales outstanding was primarily due to the impact of COVID-19.

The following table sets forth a breakdown of our general and administrative expenses in absolute amount and as a percentage of the total general and administrative expense for the periods indicated.

	Fiscal Years Ended March 31					
	2023		2022		Variance	
	RMB	%	RMB	%	RMB	%
Employee benefits	41,381,933	50.7	41,599,522	38.7	(217,589)	(0.5)
Depreciation and Amortization	6,331,847	7.8	5,998,308	5.6	333,539	5.6
Professional service fees	1,272,893	1.6	30,680,853	28.5	(29,407,960)	(95.9)
Office	2,039,932	2.5	2,766,021	2.6	(726,089)	(26.3)
Provision for trade receivables	8,655,487	10.6	5,082,725	4.7	3,572,762	70.3
Provision for obsolete inventories	(323,492)	(0.4)	4,393,629	4.1	(4,717,121)	(107.4)
Taxes and surcharges	6,537,346	8.0	5,379,934	5.0	1,157,412	21.5
Other	15,699,331	19.2	11,719,508	10.8	3,979,823	34.0
Total	**81,595,277**	**100.0**	**107,620,500**	**100.0**	**(26,025,223)**	**(24.2)**

Research and development expenses

R&D expenses increased by 50.9% from RMB211.2 million for the fiscal year ended March 31, 2022 to RMB318.7 million ($46.4 million) for the fiscal year ended March 31, 2023. The increase in R&D expenses was primarily attributable to (i) an increase of RMB11.6 million in employee benefits driven by significant growth in our R&D headcount to support the growth and development of the pipeline; (ii) an increase of RMB141.3 million in testing and clinical trial fees associated with COVID-19 vaccines and rabies vaccines; and (iii) an increase of RMB4.9 million in depreciation and amortization for property, plant and equipment and intangible assets used for R&D purpose, partially offset by a decrease of RMB50.2 million in consulting service fees relating to the research of COVID-19.

The following table sets forth a breakdown of our R&D expenses in absolute amount and as a percentage of the total R&D expenses for the periods indicated.

	Fiscal Years Ended March 31,					
	2023		2022		Variance	
	RMB	%	RMB	%	RMB	%
Testing and clinical trial fees	215,474,939	67.6	74,166,285	35.1	141,308,654	190.5
Consulting service fees	9,772,154	3.1	59,975,917	28.4	(50,203,763)	(83.7)
Employee benefits	68,073,077	21.4	56,513,100	26.8	11,559,977	20.5
Depreciation and amortization	15,736,087	4.9	10,796,480	5.1	4,939,607	45.8
Office and leasing	1,109,292	0.3	1,039,327	0.5	69,965	6.7
Other	8,534,977	2.7	8,731,154	4.1	(196,177)	(2.2)
Total	**318,700,526**	**100.0**	**211,222,263**	**100.0**	**107,478,263**	**50.9**

The following table below sets forth a breakdown of our key R&D projects.

	Fiscal Years Ended March 31,					
	2023		2022		Variance	
	RMB	%	RMB	%	RMB	%
PIKA Recombinant COVID-19 vaccine	212,197,698	66.6	127,773,439	60.5	84,424,259	66.1
PIKA rabies vaccine	60,017,584	18.8	24,272,368	11.5	35,745,216	147.3
PIKA YS-0N-001	9,201,004	2.9	16,528,066	7.8	(7,327,062)	(44.3)
PIKA HBV vaccines	12,794,983	4.0	16,438,478	7.8	(3,643,495)	(22.2)
PIKA adjuvant	7,979,196	2.5	8,171,893	3.9	(192,697)	(2.4)
YSJA™ rabies vaccine	5,949,199	1.9	7,579,877	3.6	(1,630,678)	(21.5)
Other	10,560,862	3.3	10,458,142	4.9	102,720	1.0
Total	**318,700,526**	**100.0**	**211,222,263**	**100.0**	**107,478,263**	**50.9**

Other income (expenses)

We recorded other expenses, net of RMB5.0 million ($0.7 million) for the fiscal year ended March 31, 2023, as compared to other income, net of RMB17.9 million for the fiscal year ended March 31, 2022, primarily attributable to (1) a decrease of RMB1.3 million in late fee charge of social insurance and tax; (2) an increase of RMB3.1 million in government grants; and (3) an increase of RMB28.1 million in financial expense which was primarily attributable to (i) an increase of RMB28.7 million in interest expense on bank loans and royalty fee under the Facility Agreement; (ii) an increase of RMB0.5 million interest expense on other loans.

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 expense decreased from RMB4.9 million in the fiscal year ended March 31, 2022 to RMB1.1 million ($0.2 million) in the fiscal year ended March 31, 2023, primarily due to the decrease in deferred tax assets from disposing of inventories that have been impaired in the previous period.

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.

Net loss

As a result of the foregoing, we recognized net loss of RMB145.5 million ($21.2 million), RMB106.0 million and RMB191.8 million for the fiscal year ended March 31, 2023, 2022 and 2021, respectively.

Fiscal year ended March 31, 2022 compared to fiscal year ended March 31, 2021.

Revenue

Our revenue increased by 95.7% from RMB257.0 million for the fiscal year ended March 31, 2021 to RMB502.9 million for the fiscal year ended March 31, 2022, primarily because (1) the sales period was approximately six months in the 2021 fiscal year, as we started selling the YSJA™ rabies vaccine products in October 2020; and (2) the product price increased by approximately RMB2 per dose in the 2022 fiscal year.

Cost of revenue

Our cost of revenue primarily consisted of raw material costs, staff costs, manufacturing costs and depreciation expenses. The cost increased by 96.2% from RMB59.7 million for the fiscal year ended March 31, 2021 to RMB117.1 million for the fiscal year ended March 31, 2022. The increase in costs was attributable primarily to the increase in sales volume of YSJA™ rabies vaccine products.

Gross profit and gross margin

Our gross profit increased by 95.5% from RMB197.4 million for the fiscal year ended March 31, 2021 to RMB385.9 million for the fiscal year ended March 31, 2022. The increase in gross profit was primarily due to the increase in revenue. Our gross margin was stable for the fiscal years ended March 31, 2022 and 2021.

Selling expenses

Selling expenses increased significantly from RMB73.5 million for the fiscal year ended March 31, 2021 to RMB186.0 million for the fiscal year ended March 31, 2022. The increase in selling expenses was primarily due to an increase of RMB97.7 million in promoting and marketing service fees related to the commercialization of YSJA™ rabies vaccine and an increase of RMB16.2 million in employee benefits.

The following table sets forth a breakdown of our selling expenses in absolute amount and as a percentage of the total selling expenses for the periods indicated.

	Fiscal Years Ended March 31,					
	2022		2021		Variance	
	RMB	%	RMB	%	RMB	%
Promoting and marketing service fees	162,461,330	87.3	64,770,329	88.1	97,691,001	150.8
Employee benefits	20,283,326	10.9	4,049,357	5.5	16,233,969	400.9
Others	3,255,048	1.8	4,665,573	6.4	(1,410,525)	(30.2)
Total	**185,999,704**	**100.0**	**73,485,259**	**100.0**	**112,514,445**	**153.1**

General and administrative expenses

General and administrative expense decreased by 30.7% from RMB155.3 million for the fiscal year ended March 31, 2021 to RMB107.6 million for the fiscal year ended March 31, 2022, primarily due to a decrease of RMB64.4 million in share-based compensation expenses, as most of our options had been vested before March 31, 2021, partially offset by an increase of RMB16.1 million in staff cost.

Our bad debt expenses were RMB5.1 million for the fiscal year ended March 31, 2022, representing a decrease of RMB1.9 million, or 27.4%, from RMB7.0 million for fiscal 2021. Bad debt expenses 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.

From April 1, 2022 to September 27, 2022, being the date of the auditors' opinion on our financial statement for the two fiscal years ended March 31, 2022, the subsequent settlement of our accounts receivable as of March 31, 2022 is shown in the following table:

Fiscal Year Ended March 31,	**0 – 90 days**	**90 – 180 days**	**180 – 365 days**	**>365 days**	**Total**
2022 (RMB)	73,593,680	64,397,895	58,064,055	7,184,920	203,240,550
2022 (USD)	$ 11,592,842	$ 10,144,276	$ 9,146,538	$ 1,131,804	$ 32,015,460

As of September 27, 2022, we had collected approximately RMB203 million, or 63%, of our accounts receivable as of March 31, 2022. We were not aware of any collection risk on the remaining balance.

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 decreased by 83 days, or 26.2%, from 317 days for the fiscal year ended March 31, 2021 to 234 days for the fiscal year ended March 31, 2022. The decrease in days sales outstanding was primarily due to the fact that the sales period is approximately six months in 2021 fiscal year as we started selling the YSJA rabies vaccine products since October 2020.

The following table sets forth a breakdown of our general and administrative expenses in absolute amount and as a percentage of the total general and administrative expense for the periods indicated.

	Fiscal Years Ended March 31,					
	2022		**2021**		**Variance**	
	RMB	**%**	**RMB**	**%**	**RMB**	**%**
Employee benefits	41,599,522	38.7	89,872,239	57.9	(48,272,717)	(53.7)
Depreciation and Amortization	5,998,308	5.6	9,489,983	6.1	(3,491,675)	(36.8)
Professional service fees	30,680,853	28.5	33,649,233	21.7	(2,968,380)	(8.8)
Office	2,766,021	2.6	4,020,338	2.6	(1,254,317)	(31.2)
Provision for trade receivables	5,082,725	4.7	6,998,818	4.5	(1,916,093)	(27.4)
Provision for obsolete inventories	4,393,629	4.1	—	—	4,393,629	100.0
Taxes and surcharges	5,379,934	5.0	4,004,265	2.6	1,375,669	34.4
Other	11,719,508	10.8	7,299,510	4.6	4,419,998	60.4
Total	**107,620,500**	**100.0**	**155,334,386**	**100.0**	**(47,713,886)**	**(30.7)**

Research and development expenses

R&D expenses increased significantly from RMB94.4 million for the fiscal year ended March 31, 2021 to RMB211.2 million for the fiscal year ended March 31, 2022. The increase in R&D expenses was primarily attributable to (i) an increase of RMB27.3 million in employee benefits driven by significant growth in our R&D headcount to support the growth and development of the pipeline; (ii) an increase of RMB53.7 million in testing and clinical trial fees associated with COVID-19 vaccines, rabies vaccines and anticancer vaccines; (iii) an increase of RMB28.5 million in consulting service fees relating to the research of COVID-19; and (iv) an increase of RMB4.5 million in depreciation and amortization for property, plant and equipment and intangible assets used for R&D purposes.

The following table sets forth a breakdown of our R&D expenses in absolute amount and as a percentage of the total R&D expenses for the periods indicated.

	Fiscal Years Ended March 31,					
	2022		2021		Variance	
	RMB	%	RMB	%	RMB	%
Testing and clinical trial fees	74,166,285	35.1	20,480,320	21.7	53,685,965	262.1
Consulting service fees	59,975,917	28.4	31,492,876	33.4	28,483,041	90.4
Employee benefits	56,513,100	26.8	29,178,337	30.9	27,334,763	93.7
Depreciation and amortization	10,796,480	5.1	6,331,638	6.7	4,464,842	70.5
Office and leasing	1,039,327	0.5	3,446,146	3.7	(2,406,819)	(69.8)
Others	8,731,154	4.1	3,457,827	3.6	5,273,327	152.5
Total	**211,222,263**	**100.0**	**94,387,144**	**100.0**	**116,835,119**	**123.8**

The following table below sets forth a breakdown of our key R&D projects.

	Fiscal Years Ended March 31,					
	2022		2021		Variance	
	RMB	%	RMB	%	RMB	%
PIKA Recombinant COVID-19 vaccine	127,773,439	60.5	33,903,400	35.9	93,870,039	276.9
PIKA rabies vaccine	24,272,368	11.5	13,718,774	14.5	10,553,594	76.9
PIKA YS-0N-001	16,528,066	7.8	4,312,590	4.6	12,215,476	283.3
PIKA HBV vaccines	16,438,478	7.8	7,536,556	8.0	8,901,922	118.1
PIKA adjuvant	8,171,893	3.9	26,036,582	27.6	(17,864,689)	(68.6)
YSJA™ rabies vaccine	7,579,877	3.6	3,939,781	4.2	3,640,096	92.4
Others	10,458,142	4.9	4,939,461	5.2	5,518,681	111.7
Total	**211,222,263**	**100.0**	**94,387,144**	**100.0**	**116,835,119**	**123.8**

Other income (expenses)

We recorded other income, net of RMB17.9 million for the fiscal year ended March 31, 2022, as compared to other expenses, net of RMB48.5 million for the fiscal year ended March 31, 2021, primarily attributable to (1) a decrease of RMB24.34 million in late fee charge of social insurance and tax; and (2) an increase of RMB19.5 million in government grants, which was partially offset by a decrease of RMB4.4 million in other income; (3) an decrease of RMB5.0 million in financial expense which was primarily attributable to (i) a decrease of RMB3.0 million in interest expense on bank loans, as interest rate on bank loans decreased from 8% and 8.0475% in the fiscal year ended March 31, 2022 to 5.3% and 5.655% in the fiscal year ended March 31, 2022 and repayment by us of RMB49.6 million in bank loan in the fiscal year ended March 31, 2022; (ii) a decrease of RMB2.0 million in interest expense on borrowings from our employees; and (iii) a decrease of RMB22.0 million in the transaction cost for issuance of convertible notes and preferred shares in the fiscal year ended March 31, 2021.

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 expense decreased from RMB17.5 million in the fiscal year ended March 31, 2021 to RMB4.9 million in the fiscal year ended March 31, 2022, primarily due to the decrease in deferred tax assets from disposing of inventories that have been impaired in the previous period.

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.

Net loss

As a result of the foregoing, we recognized net loss of RMB106.0 million and RMB191.8 million for the fiscal year ended March 31, 2022 and 2021, respectively.

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,			
	2023		2022	2021
	RMB	US$	RMB	RMB
Net cash used in operating activities	(182,469,396)	(26,553,749)	(173,545,357)	(246,610,437)
Net cash used in investing activities	(56,981,720)	(8,292,230)	(298,923,958)	(104,238,941)
Net cash provided by financing activities	317,449,926	46,196,709	364,558,145	739,258,696
Effect of foreign exchange rate on cash and cash equivalents	21,303,512	3,100,180	(11,478,411)	(2,674)
Net increase (decrease) in cash and cash equivalents	99,302,322	14,450,910	(119,389,581)	388,406,644
Cash and restricted cash at the beginning of the fiscal year	271,067,503	39,446,935	390,457,084	2,050,440
Cash and restricted cash at the end of the fiscal year	370,369,825	53,897,845	271,067,503	390,457,084

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.

As of March 31, 2023, 2022 and 2021, our principal source of liquidity was our cash balance of RMB370.4 million ($53.9 million), RMB271.1 million and RMB390.5 million, respectively, which was held for working capital purposes. We incurred a net loss after tax of RMB145.5 million ($21.2 million), RMB106.0 million and RMB191.8 million for the fiscal years ended March 31, 2023 and 2022, 2021, 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 RMB182.5 million ($26.6 million) and RMB173.5 million in the fiscal years ended March 31, 2023 and 2022, respectively, primarily due to the significant R&D expenses 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. 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 Warrant will become exercisable for one Ordinary Share at $11.50. Therefore, if and when the trading price of the Ordinary Shares is less than $11.50, we expect that holders of Warrants would not have the financial incentive to exercise their Warrants. We could receive up to 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 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.”

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, 2023, 2022 and 2021, our working capital was RMB377.2 million ($54.9 million), RMB288.9 million and RMB388.2 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 RMB182.5 million ($26.6 million) for the fiscal year ended March 31, 2023 was primarily related to a net loss for the fiscal year of RMB145.5 million ($21.2 million) adjusted for certain non-cash items, which included deferred income taxes RMB1.1 million ($0.2 million), depreciation of RMB29.7 million ($4.3 million), amortization of intangible assets of RMB7.0 million ($1.0 million), share- based compensation expense of RMB3.5 million ($0.5 million), bad debt provision of trade receivable and inventories of RMB10.8 million ($1.6 million), reversal of inventories to net realizable value of RMB0.7 million ($0.1 million), non-cash lease expense of RMB4.4 million ($0.6 million), and increase of fair value change of warrant liabilities of RMB0.02 million ($0.003 million). The net changes in operating assets and liabilities of RMB92.7 million were primarily related to 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 grant of RMB6.4 million, and payment of lease liabilities of RMB4.6 million.

Net cash used in operating activities of RMB173.5 million for the fiscal year ended March 31, 2022 was primarily related to a net loss for the fiscal year of RMB106 million adjusted for certain non-cash items, which included Deferred income taxes RMB4.9 million , depreciation of RMB24.5 million, amortization of intangible assets of RMB6.7 million, loss on disposal of property, plant and equipment of RMB0.3 million, share- based compensation expense of RMB7.8 million, impairment of trade receivable and inventories of RMB5.1 million, write-down of inventories to net realizable value of RMB4.4 million, and non-cash lease expense of RMB3.8 million. The net changes in operating assets and liabilities of RMB124.9 million were primarily related to an increase in inventories of RMB89.5 million due to increased demand in rabies vaccine and our decision to continue to increase our inventory level to avoid any unpredictable logistics disruption or rising cost of raw material from the ongoing impact of COVID-19 on the global supply chain, an increase in trade receivables of RMB99.1 million from increased sales of the rabies vaccine in 2022 fiscal year, a decrease in amounts due from related parties of RMB30.1 million, a decrease in prepaid expenses and other current assets of RMB59.2 million due primarily to increased prepayments for construction in progress, an increase in trade payables of RMB14.4 million as a result of extending the accounting period for customers, which were partially offset by a decrease in accrued expenses and current liabilities of RMB35.6 million due to decrease expenditure on staff costs and increase expenditure for construction in progress, decrease in deferred government grant of RMB0.7 million, and payment of lease liabilities of RMB3.8 million.

Net cash used in operating activities of RMB246.6 million for the fiscal year ended March 31, 2021 was primarily related to a loss before tax for the year of RMB191.8 million, adjusted for certain non-cash items, which included deferred income tax of RMB17.5 million, depreciation of RMB22.2 million, amortization of intangible assets of RMB5.7 million, share-based compensation expense of RMB76.8 million, impairment of trade receivable of RMB6.4 million, write-down of inventories to net realizable value RMB1.1 million, and non-cash lease liability of RMB2.2 million. The net changes in operating assets and liabilities of RMB186.7 million were primarily related to an increase in inventories of RMB68.7 million due to increased demand in rabies vaccine and our decision to continue to increase our inventory level to avoid any unpredictable logistics disruption or rising cost of raw material from the ongoing impact of COVID-19 on the global supply chain, an increase in trade receivables of RMB220.7 million from increased an sales of the rabies vaccine in 2021 fiscal year, an increase in amounts due from related parties of RMB3.1 million, an increase in prepaid expenses and other current assets of RMB146.8 million primarily due to increase in advance to suppliers, a decrease in trade payables of RMB4.4 million, payment of income tax for previous years of RMB34.1 million, and payment of lease liabilities of RMB2.2 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 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).

Net cash used in investing activities was RMB298.9 million for the fiscal year ended March 31, 2022, which consisted primarily of payment for purchase of items of property, plant and equipment of RMB295.3 million and partial payment for purchase of intangible assets of RMB3.6 million.

Net cash used in investing activities was RMB104.2 million for the fiscal year ended March 31, 2021,which consisted primarily of payment for purchase of items of property, plant and equipment of RMB104.9 million, partially offset by a cash inflow from proceeds from disposal of property, plant and equipment of RMB0.6 million.

Financing activities

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 RMB146.5 million ($21.3 million) in repayment of bank.

Net cash generated from financing activities was RMB364.6 million for the fiscal year ended March 31, 2022, which consisted primarily of RMB414.1 million in proceeds from bank and other borrowings, partially offset by RMB49.6 million in repayment of bank.

Net cash generated from financing activities was RMB739.3 million for the fiscal year ended March 31, 2021, which consisted primarily of RMB729.4 million in proceeds from issuance of mezzanine equity, RMB32.3 million in proceeds from bank and other borrowings, and RMB299.8 million in proceeds of loans from related parties, partially offset by RMB160.4 million in repayment of bank and other borrowings, RMB163.3 million in repayment of related parties, and RMB1.6 million in shareholders' contributions.

Contractual Obligations

On September 13, 2021, we entered into a credit facility of RMB100 million with China Guangfa Bank Co., Ltd. Shenyang Branch for three years to finance our working capital requirements. We drew RMB41.2 million from October 14 2022 to January 13, 2023 with interest at 5.66%, which is due from October 13, 2023 to December 16, 2023. In June, 2023, we repaid RMB31.7 million in advance.

On July 12, 2021, we entered into a credit facility of RMB140 million with Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch for three years to finance our working capital requirements. We drew down RMB83.0 million from June 30, 2022 to December 13, 2022 with interest at 5.30%, which is due from June 29, 2023 to December 12, 2023. In April and July, 2023, we repaid RMB20.9 million and RMB32.4 million in advance, respectively.

On May 2, 2020, we borrowed RMB1,103,609 (US$166,400) with interest at 1.00% from Citi Bank. The loan was due on May 1, 2022. Before March 31, 2022, we repaid approximately RMB869,000 (US$129,422). As of March 31, 2022, the balance of approximately RMB235,000 (US$36,978) was outstanding, which amount was repaid in full in May, 2022.

On March 16, 2022, we entered into a facility agreement with R-Bridge Healthcare Fund, LP, as agent, to finance RMB274,868,000 (US$40,000,000) for 54 months with interest at 4.00%. We shall repay the loan in instalments by repaying on each Repayment Date which means the fifth business day after each financial quarter date an amount equal to the relevant percentage of the aggregate outstanding principal amount of the loan as at the end of the Availability Period as set out in the table below:

Repayment Date	**Repayment Instalment**
April 7, 2025	6,400,000
July 7, 2025	6,400,000
October 7, 2025	6,400,000
January 7, 2026	6,400,000
April 7, 2026	6,400,000
July 7, 2026	8,000,000
Total	**40,000,000**

We shall pay accrued interest on the Loan on each Payment Date. As of March 31, 2023, we accrued approximately RMB23.4 million (US$3.4 million) of interest.

If we fail to pay any amount payable by us under the Facility Agreement on our due date, interest shall accrue on the unpaid sum from the due date to the date of actual payment at interest of 3% higher than the rate which would have applied if the unpaid sum had not become due.

Under the terms of the Facility Agreement, we and Agent also entered into a Deed, pursuant to which we will pay to Agent, the Royalties on the Products of YSJA rabies vaccine (royalty products) as contingent interest in addition to the payments made to Agent under the Facility Agreement, on the terms and subject to the conditions of the Deed. We are obliged to pay royalties to such agent as contingent interest for the facility based upon our annual net sales of rabies vaccines by multiplying the royalty rate below by the corresponding amount incremental net sales for that financial year.

During the royalty term until (but excluding) the date we repay all outstanding amounts under the Facility Agreement (the "Royalty Reduction Date"), the royalty rates for each financial year shall be as follows (with a cap of RMB60,000,000 per financial year):

Net Sales Tiers	**Royalty Rate**
For that portion of annual net sales of Royalty Products in a financial year that are less than or equal to RMB500 million	1.5%
For that portion of annual net sales of Royalty Products in a financial year that are greater than RMB500 million but less than or equal to RMB1 billion	3.0%
For that portion of annual net sales of Royalty Products in a financial year that are greater than RMB1 billion	3.5%

If the Royalty Reduction Date occurs after March 18, 2024 and any royalties payable have been duly paid, we shall:

(a) pay the reduced royalty rates for the remainder of the royalty term as follows (with a cap of RMB24 million per financial year), or

Net Sales Tiers	Royalty Rate
For that portion of annual net sales of Royalty Products in a financial year that are less than or equal to RMB500 million	0.6%
For that portion of annual net sales of Royalty Products in a financial year that are greater than RMB500 million but less than or equal to RMB1 billion	1.2%
For that portion of annual net sales of Royalty Products in a financial year that are greater than RMB1 billion	1.4%

(b) at its option, pay an amount equal to 4% of the principal amount (the "Royalty Repurchase Amount") prepaid on the Royalty Reduction Date pursuant to the Facility Agreement in addition to the payment of the applicable prepayment fee as defined in the Facility Agreement), then, no royalties shall be due and owing to Agent.

The term of royalty commenced April 1, 2022 and will expire till the last day of the relevant financial quarter within which the earliest of the following occurs:

(a) the date of the payment of the Royalty Repurchase Amount;

(b) the Royalty Reduction Date, if the Royalty Reduction Date occurs on or prior to March 18, 2024;

(c) September 30, 2026; and

(d) the expiration of the Facility Agreement.

On January 13, 2023, we entered into a credit facility of RMB40 million with China CITIC Bank Shenyang Tiexi Branch, due on November 29, 2023, to finance our working capital requirements. We drew RMB23.6 million from January 18, 2023 to February 17, 2023 with interest at 5.00%, which is due from October 13, 2023 to November 9, 2023.

On May 6, 2022, China CITIC Bank Shenyang Tiexi Branch issued one letter of credit of RMB5.0 million to us with interest at 3.25%. As of March 31, 2023, we had RMB4.7 million in letters of credit issued, which is due from May 19, 2023 to July 17, 2023. From May to July 2023, we repaid RMB4.7 million.

From September 9, 2022 to November 25, 2022, we borrowed RMB31.3 million in total with interest at 4.00% from China Construction Bank Shenyang Heping Branch for one year. The loan will be due from September 8, 2023 to November 24, 2023. On June 5, 2023, we repaid RMB9.7 million in advance.

On January 16, 2023, we borrowed RMB988,000 with interest at 3.90% from China Construction Bank Shenyang Heping Branch for one year. The loan will be due on January 12, 2024.

On March 17, 2023, we borrowed RMB4.4 million with interest at 4.00% from China Construction Bank Shenyang Heping Branch for 18 months. The loan will be due on September 16, 2024.

On November 8, 2022, we borrowed RMB26.0 million with interest at 5.00% from Zhongguancun Technology Leasing Co., Ltd for 36 months. We 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. We repaid RMB2.9 million from December 2022 to March 2023. The balance of RMB23.1 million is outstanding, of which RMB8.6 million is due within one year. From April 13 to July 17, we repaid RMB2.9 million according to the arrangement.

We recorded RMB32.0 million, RMB2.8 million and RMB5.8 million of interest expense for the fiscal year ended March 31, 2023, 2022 and 2021, respectively.

Lease liabilities

A summary of our operating lease commitments as of March 31, 2023 is as follows:

Year Ended March 31,	(RMB)	(US$)
2024	5,178,993	$ 753,670
2025	5,040,835	733,564
2026	1,526,270	222,110
Total lease payments	11,746,098	1,709,344
Less: Interest	(643,661)	(93,669)
Present value of operating lease liabilities	11,102,437	$ 1,615,675

As of March, 31, 2023, the outstanding, discounted amount of lease liabilities was RMB11.1 million ($1.6 million) which was related to the lease agreements for two premises in China, one premises in Singapore and one premises in United States.

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 that 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, we have received RMB1,636,755 from Hebei Defense Biological Products Supply Center, and the balance of RMB829,052 may be received in fiscal 2024.

In 2019, Liaoning Yisheng filed a sales contract dispute with Chaoyang Center for Disease Control and Prevention. The Supreme People's Court of Liaoning supported the Liaoning Yisheng's claim that the defendant Chaoyang Center for Disease Control and Prevention should pay RMB416,900 for Liaoning Yisheng vaccine. To the date, we received RMB380,000 from Chaoyang Center for Disease Control and Prevention, and the balance of RMB36,900 may be received in the second half of 2023.

In 2023, Liaoning Yisheng was involved in a dispute with Shenyang Haoyu Landscape Engineering Co., Ltd which claimed that Liaoning Yisheng should pay RMB278,707 for the greening construction. As the proceedings are in the early stages, there is considerable 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.

We were also involved in certain other labor disputes as of March 31, 2023. As the proceedings are in the early stages or the second appeal, there is considerable 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 of our own. 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 RMB582.0 million and RMB515.7 million ($75.1 million) as of March 31, 2022 and 2023, respectively. In addition, pursuant to the relevant PRC laws, enterprises in the PRC have to make appropriation 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 YS 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, 2021, 2022 and 2023, we transfer cash proceeds to Liaoning Yisheng were RMB428.5 million, RMB291.1 million and nil. 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 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."

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 has 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 three fiscal years ended March 31, 2021, 2022 and 2023, we did not transfer any cash proceeds to any of our PRC subsidiaries except for the cash transfers within us in connection with the paid-in capital in our PRC subsidiaries. $59,900,000 of the registered capital was paid up by HK Yisheng to Liaoning Yisheng during the fiscal year ended March 31, 2021 and $45,099,071.49 of the registered capital was paid up by HK Yisheng to Liaoning Yisheng during the fiscal year ended March 31, 2022. No registered capital was paid up by HK Yisheng to Liaoning Yisheng during the year ended March 31, 2023.

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

We are a private company with limited accounting personnel and other resources to address our ICFR. Our management has not completed an assessment of the effectiveness of our ICFR and our independent registered public accounting firm has not conducted an audit of our ICFR. In connection with the audit of our consolidated financial statements as of and for the years ended March 31,2023 and 2022, we and our independent registered public accounting firm identified a material weakness in our ICFR as of March 31, 2023. As defined in the standards established by the PCAOB, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

The material weakness identified relates to lack of sufficient competent financial reporting and accounting personnel with appropriate understanding of U.S. GAAP to design and implement formal period-end financial reporting policies and procedures to address complex U.S. GAAP technical accounting issue; and to prepare and review our consolidated financial statements and related disclosures in accordance with U.S. GAAP and financial reporting requirements set forth by the SEC. To remediate our identified material weakness, hawse have adopted measures to improve our ICFR, including, among others: (i) hiring additional qualified accounting and financial personnel with appropriate knowledge and experience in U.S. GAAP accounting and SEC reporting, and (ii) organizing regular training for our accounting staffs, especially training related to U.S. GAAP and SEC reporting requirements. We also plan to adopt additional measures to improve our ICFR, including, among others, creating U.S. GAAP accounting policies and procedures manual, which will be maintained, reviewed and updated, on a regular basis, to the latest U.S. GAAP accounting standards, and further hiring executive accounting personnel with strong knowledge and experience in U.S. GAAP accounting and SEC reporting.

However, we cannot assure you that all these measures will be sufficient to remediate our material weakness in time, or at all. See "Item 3. Key Information—D. Risk Factors—Risks Related to Ownership of the Ordinary Shares—If we fail to remediate our material weakness 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.

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."

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, 2022 to March 31, 2023 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.

E. Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements 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 consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in Note 3 to the audited consolidated financial statements 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.

Revenue from Contracts with Customers

We follow 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 we expect 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 we satisfy a performance obligation

We are principally engaged in the research, development, manufacturing and sale of vaccines and therapeutic biologics. Our revenues primarily streams from the sales of vaccines.

The core principle underlying the revenue recognition ASC 606 is that we recognize revenue to represent the transfer of vaccines to customers in an amount that reflects the consideration to which we expect to be entitled in such exchange. This requires us to identify contractual performance obligations and determine whether revenue should be recognized at a point in time or over time. Our 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, we evaluate 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. We sell vaccines to the customers, and it obtains control of the vaccines before customer acceptance confirmation. Therefore, we are a principal, and the revenues should be recognized according to the gross method.

Leases

Under ASC Topic 842, Leases ("ASC 842"), we determine if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, we do not recognize a right-of-use ("ROU") asset or lease liability. Our operating leases are recognized on our consolidated balance sheets as noncurrent assets, current liabilities and noncurrent liabilities. We do not have any finance leases.

ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our 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 our leases typically do not provide an implicit rate, we use an estimate of our 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 we 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, we record 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, we record rents in administrative expenses.

Government grants

Government grants represent primarily subsidies received from PRC governments for operating a business in their jurisdictions and in compliance with specific policies promoted by the government authorities. Our 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 us, receipt of such subsidy is not contingent upon any further actions or performance of us 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 recognized in income when the conditions are met. Other subsidies are recognized as other income upon receipt as further performance by us is not required.

Government grants for “R&D” are recognized as a reduction to R&D expenses when the conditions attached to the grants are met or recognized as government grants recognized in income 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 a reduction to the related depreciation and amortization expenses in the same manner as the property, plant and equipment are depreciated.

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.

Unless otherwise disclosed, the FV of our financial instruments including cash, accounts receivable, advances to suppliers, amounts due from related parties, prepaid expenses and other current assets, short-term bank loans and other loans, accounts payable, warrant liabilities, and accrued expenses and other current liabilities approximate their recorded values due to their short-term maturities. The FV of longer-term leases approximates their recorded values as their stated interest rates approximate the rates currently available.

Our non-financial assets, such as property and equipment would be measured at FV only if they were determined to be impaired.

Impairment of Long-lived Assets

We review long-lived assets, including definitive-lived intangible assets and property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When such events occur, we assess 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 we identify an impairment, we reduce the carrying amount of the asset group to the 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 in general and administrative expenses in the consolidated statements of operations. We use estimates and judgments in our 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 no longer depreciated. We did not record any impairment charges during the years ended March 31, 2023, 2022 and 2021.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

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 composed of seven directors.

Name	Age	Position
Mr. Yi Zhang	66	Director and Chairperson
Dr. Hui Shao	55	Director, President and Chief Executive Officer
Mr. Bo Tan	49	Director
Dr. Ajit Shetty	77	Independent Director
Dr. Viren Mehta	73	Independent Director
Dr. Stanley Yi Chang	64	Independent Director
Mr. Shaojing Tong	52	Independent Director
Dr. Zenaida Reynoso Mojares	65	Chief Medical Officer
Ms. Chunyuan Wu	45	Chief Financial Officer
Dr. Yuan Liu	37	Head of vaccine research
Mr. Gang Li	42	Head of marketing and sales

Mr. Yi Zhang is our founder and has served as the chairman of our board since November 16, 2020 and is serving as our Chairman. Mr. Zhang has over 30 years of experience in research, development and commercialization of immunological biologics and vaccines. Since the inception of Yisheng Biopharma Co., Ltd. ("Yisheng Biopharma"), our predecessor in February 2010, Mr. Zhang has been our director. He was the chief executive officer of Yisheng Biopharma from February 2010 to February 2018. Mr. Zhang has been the chairman of the board of Liaoning Yisheng since April 2005. He was the inventor of the first aluminum-free rabies vaccine and human rabies immunoglobulin in China. He was also the project leader of national 863 scientific project "SARS Immunoglobulin" and several other national key medical innovation projects funded by Chinese government. From June 1986 to May 2002, Mr. Zhang served as a physician and as the division head of Kaifeng Suburb CDC. From August 1981 to May 1986, Mr. Zhang was a physician for epidemic prevention in Zhongmou County CDC.

Mr. Zhang graduated from Kaifeng Health Science School in October 1981 with a major in clinical medicine. Mr. Zhang is also the director in the Henan Red Cross Society.

Dr. Hui Shao has served as our executive director and chief executive officer since December 31, 2020 and is serving as our Director and Chief Executive Officer. 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 and AICPA holder in the State of Washington, the United States.

Mr. Bo Tan, is serving as our Director. Mr. Tan has over 20 years of extensive experience in the financial and pharmaceutical industries. He is the founding partner of Hannut Capital since 2021 and was the President and Chief Financial Officer of 3S Bio from December 2016 to December 2019. During his tenure at 3S Bio, Mr. Tan led the privatization of 3SBio and its re-listing in Hong Kong in 2015, as well as the acquisition and integration of Sciprogen, Sirton (Italy), Wanma and CP Guojian. From 2015 to 2019, Mr. Tan was voted the "Best CFO" for consecutive years in the Institutional Investor All-Asia Executive Team poll. Before joining 3S Bio, Mr. Tan served as the executive director and a member of Investment Committee of Bohai Industrial Investment Fund Management Company, a PRC-based private equity firm, and presided over the investment in The Chengdu Commercial Bank, from April 2007 to September 2008. Prior to that, Mr. Tan served as a vice president in the equity research division of Lehman Brothers Asia Limited from March 2006 to March 2007 and as a senior analyst at Macquarie Securities Asia in Hong Kong from October 2004 to February 2006. Mr. Tan is widely acclaimed for his stellar track record of combining business operations and capital market prowess and has long-standing strategic relationships with major MNCs.

Mr. Tan received his bachelor's degree in economics from Renmin University of China in July 1994, Master's degree in Economics from the University of Connecticut in December 1996 and a Master of International Management from Thunderbird School of Global Management in August 1998.

Dr. Ajit Shetty, has served as our independent non-executive director since January 2021 and is serving as our independent director. Dr. Shetty has served as a director of Actinium Pharmaceuticals, Inc., a company listed on the New York Stock Exchange (ATNM.US), since March 2017. He has also been a director of Agile Therapeutics, Inc., a company listed on the Nasdaq (AGRX.US), since February 2016. He has been an independent director of reMYND NV since August 2012. From February 2004 to February 2012, Dr. Shetty served as the chairman of the board of directors of Janssen Pharmaceutica NV, a pharmaceutical company and subsidiary of Johnson & Johnson, a company listed on the New York Stock Exchange (JNJ.US). From July 2007 to February 2012, he served as the Global Head of the enterprise supply chain in Johnson & Johnson and was a member of the corporate operating committee.

Dr. Shetty is a member of the Board of Trustees of Carnegie Mellon University. In 2004, Dr. Shetty was elected as Manager of the Year in Flanders, Belgium. In 2007, Dr. Shetty received the title of Baron for his exceptional merits and contribution to the country of Belgium. In 2008, he was conferred an honorary doctorate by Manipal University (India). In 2016, Dr. Shetty was named as Chairperson of the Flemish Institute of Biotechnology (VIB), a Belgium-based life sciences research institute with a focus on translating scientific results into pharmaceutical, agricultural and industrial applications.

Dr. Shetty received a Ph.D. degree in metallurgy and a master's degree in natural sciences from Trinity College, Cambridge University in April 1972 and June 1968, respectively. He also received an M.B.A. degree from Carnegie Mellon University in June 1974.

Dr. Viren Mehta, has served as our independent non-executive director since January 2021 and is serving as our independent director. Dr. Mehta has an extensive experience in investment research and strategic advisory services, focusing on the pharmaceutical and biotechnology industry. He is the founder and managing member of Mehta Partners, LLC since February 1997. He has been a director of Onconova Therapeutics Inc., a company listed on Nasdaq (ONTX.US), since February 2004. From April 2013 to December 2017, Dr. Mehta served as the executive chair and co-founder of Gather Health Ltd, one of the early telehealth initiatives based in Hong Kong. Dr. Mehta served as a director of BlinkBio Inc. from September 2010 to December 2020. From November 1999 to June 2010, Dr. Mehta served as a director of OSI Pharmaceuticals Inc., when Astellas of Japan acquired OSI for $4 billion. Dr. Mehta also actively works with not-for-profit-enterprises around the world focused on education, ecology, and healthcare.

Dr. Mehta received his Ph.D. degree of pharmacy from the University of Southern California in August 1974 and his M.B.A. degree from the University of California, Los Angeles in December 1980.

Dr. Stanley Yi Chang, has served as our independent non-executive director since January 2021 and is serving as our independent director. Dr. Chang is currently an independent non-executive director of Nongfu Spring Co., Ltd., a company listed on the main board the Stock Exchange (9633.HK). Dr. Chang is currently a standing council member of China Institute of Internal Audit, and a member of Auditing Expert Panel of Asian Development Bank. He is also the Audit Committee Chair (Board Member) of CoWealth Co. (603122.SH). Dr. Chang has been a professor at Shanghai Advance Institute of Finance of Shanghai Jiaotong University since July 2018. He was a professor at National Taiwan University from August 2016 to June 2018. Prior to that, Dr. Chang had successively served as the chief operating officer of MarcumBP where he also led its China Advisory Services; managing partner of China Advisory Services and global business risk services leader for Grant Thornton; and partner of business risk services and Asia Pacific life sciences leader for Ernst & Young from September 2007 to October 2016.

Dr. Chang received his Ph.D. degree in accounting from Texas Tech University in the United States in August 1987; his master's degree in accounting from University of Missouri-Columbia in the United States in August 1983; and his bachelor's degree in business administration from National Taiwan University in June 1980. Dr. Chang is a Certified Public Accountant of Texas, United States.

Mr. Shaojing Tong, is serving as our independent director. Mr. Tong, who has nearly 20 years of experience in investment banking focusing on the global healthcare sector, has acquired an in-depth understanding of both the U.S. and Asian healthcare markets. He has served as the chief financial officer of InnoCare Pharma Limited, a company listed on the Stock Exchange (9969.HK) since June 2019. From July 2013 to May 2019, Mr. Tong was employed by UBS AG with his last position as executive director in the investment banking research department. From May 2008 to May 2013, Mr. Tong was employed by Bank of America Merrill Lynch with his last position as director in global research. From June 2001 to April 2008, Mr. Tong served as an equity analyst in global pharmaceutical equity research at Mehta Partners.

Mr. Tong received his bachelor's degree in material science and engineering from the University of Science and Technology of China (Hefei) in July 1993, his master's degree in chemistry from the University of Pittsburgh in August 1996 and an M.B.A. degree in finance from New York University in May 2001.

Dr. Zenaida Reynoso Mojares, has served as our chief medical officer since January 2022 and is serving as our Chief Medical Officer. She is responsible for the strategy, direction and execution of the R&D and global clinical trial programs. Dr. Mojares is responsible for the strategy, direction and execution of the R&D and global clinical development and clinical operations. Dr. Mojares is a highly accomplished medical professional with diverse experience in medical, clinical research, pharmacovigilance and public health in both private and national government sectors. From July 2021 to January 2022 and from August 2020 to June 2021, she served as the Chief Medical Officer and the Head of Clinical Development & Regulatory department respectively at the International Vaccine Institute in Seoul, South Korea. Her responsibilities included execution and delivery of funded clinical trials, supporting the development of new project opportunities, supervising the clinical team and developing clinical strategy. From June 2017 to July 2020, she served as the Regional Medical Director at Takeda Pharmaceuticals International AG, Vaccines Business Unit in Zurich, Switzerland. From March 2016 to June 2017, she served as the Senior Clinical Research & Development Lead at GSK Vaccines in Singapore and eventually relocated to GSK Vaccines Srl, R&D Center in Italy and was responsible for clinical development activities. From March 2015 to February 2016, she served as the chief medical officer, ad interim and lead regional physician in GlaxoSmithKline Pte Limited Singapore. From July 2011 to March 2015, she served several positions including Region International Physician Lead in Novartis Asia Pacific Pharmaceuticals Pte Ltd.

Dr. Mojares received her bachelor's degree of Science in General from University of Santo Tomas in 1979 and received her Doctor of Medicine degree from Perpetual Help College of Medicine in 1990. She is a Diplomate of the Philippine College of Gerontology & Geriatrics in 2004. She also received a Master of Science degree in Vaccinology and Pharmaceutical Clinical Development from Universita degli Studi di Siena and Novartis Vaccines & Diagnostics, Siena Italy, in April 2011 and a master's degree in public health (MPH) from University of the Philippines in 2004.

Ms. Chunyuan Wu, has served as our chief financial officer since December 31, 2020 and is serving as our Chief Financial Officer. She is responsible for the overall finance management, including designing and developing objectives on tax planning, structuring bank loans for its subsidiaries, overseeing daily operation of the financial team, and working with external advisers for business expansion. Ms. Wu served as the chief financial officer of Yisheng Biopharma from February 2018 to December 2020, after five years of serving as the financial controller at the same company since February 2013. From September 2010 to December 2012, Ms. Wu was the financial controller of Jilin Milk Ground Group where she oversaw the financial operation of the company and was responsible for the preparation of the financial statements in accordance with IFRS and PRC GAAP. From October 2005 to August 2010, Ms. Wu served as a senior auditor at Ernst & Young. From January 2005 to September 2005, she served as an auditor of Shine Wing.

Ms. Wu graduated from Business School of Washington State University (Pullman) in May 2001 with double majors in accounting and finance and minor in economics. Ms. Wu has achieved FCCA and CPABC.

Dr. Yuan Liu, has served as our head of vaccine research since January 2019 and is serving as our head of vaccine research. 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.

Mr. Gang Li, has served as our head of marketing and sales since March 2019 and is serving as our head of vaccine research. He is responsible for the management of the overall marketing system. Prior to joining YS Group, he had served in GlaxoSmithKline (China) Investment Co., Ltd. since July 2009, responsible for the daily business management of the certain vaccine in North China. From May 2009 to June 2009, he served as a medical information specialist in Pfizer Investment Co., Ltd. From September 2006 to April 2009, he served as a pharmaceutical representative of GSK. From July 2003 to July 2006, he served in the sales department of Shenwei Pharmaceutical Ltd.

Mr. Li received his bachelor's degree in Hebei Medical University in July 2003. He received an M.B.A. degree in Sorbonne Business School in May 2018.

B. Compensation

In the fiscal year ended March 31, 2023, we paid RMB10.4 million and RMB0.4 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.

Share Incentive Plans

On December 31, 2020, our board of directors adopted the 2020 Share Incentive Plan of YS Group (the "YS Biopharma 2020 Plan") for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with us. Pursuant to such plan, we are entitled to grant awards to our directors, employees and consultants with rights to subscribe for up to 35,000,000 underlying ordinary shares of YS Biopharma (prior to the YS Biopharma Share Consolidation).

We have approved and adopted the amended and restated YS Biopharma 2020 Share Incentive Plan (the "YS Biopharma 2022 Plan") to resume all the terms and conditions of the YS Biopharma 2020 Plan to continue to incentivize our directors, employees and consultants of and our subsidiaries for future development of our business and R&D activities.

The following summarizes the material terms of the YS Biopharma 2022 Plan:

Shares Subject to the Plan. Initially, the maximum number of Ordinary Shares that may be issued under the YS Biopharma 2022 Plan will be 6,656,582 Ordinary Shares. If an award terminates, expires, or lapses for any reason without having been exercised or settled in full, the number of shares subject to the award shall again be available for the grant of an award pursuant to the YS Biopharma 2022 Plan.

Types of awards. The plan administrator shall determine the type or types of award(s) to be made to each selected eligible person. The types of awards that may be granted under the YS Biopharma 2022 Plan include share options, share appreciation rights, restricted share units and other awards approved by the plan administrator.

Plan Administration. The YS Biopharma 2022 Plan shall be subject to the administration of our Board or one or more committees or person as authorized and appointed by our Board. Pursuant to the YS Biopharma 2022 Plan, the committee shall be comprised solely of one or more directors or such number of directors as may be required under applicable laws as the plan administrator. The plan administrator shall have the right to (i) determine eligibility and the particular eligible persons who will receive an award under the YS Biopharma 2022 Plan; (ii) grant awards, determine the price and the number of securities and other terms (e.g., any performance criteria upon which the exercise of an option or the settlement of an award is conditioned) of awards granted thereto; (iii) approve the forms of award agreements; (iv) construe and interpret the terms of the YS Biopharma 2022 Plan and any agreements in relation to the YS Biopharma 2022 Plan; (v) prescribe, amend and rescind rules and regulations relating to the Plan; (vi) modify or amend each award; and (vi) make such other decisions or take any other action as we shall deem appropriate in the administration of the YS Biopharma 2022 Plan.

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 YS Biopharma 2022 Plan.

Eligibility. Persons eligible to participate in the YS Biopharma 2022 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.

Effect of termination of services. Unless our Board otherwise expressly provides, (1) to the extent an outstanding option granted under such plan has not become vested and exercisable on the date the participant's employment by or service to the proposed listing group terminates, the option to the extent unvested and unexercisable shall terminate, and (2) any shares subject to a restricted share award that remain subject to restrictions at the time the participant's employment by or service to the proposed listing group terminates shall not vest and we shall have the right to reacquire any such unvested shares subject to such award in such manner and on such terms as the administrator provides, which terms shall include return or repayment of the lower of the fair market value or the original purchase price of the restricted shares, without interest, to the participant to the extent not prohibited by law.

Performance Criteria. YS Biopharma 2022 Plan allows the administrator to establish the performance criteria when granting stock options on the basis of any one of, or combination of, earnings per share, cash flow, total shareholder return, gross revenue, revenue growth, operating income (before or after taxes), net earnings, return on equity, return on assets, return on investment, cost containment or reduction. The applicable performance measurement period may not be less than three months nor more than 10 years.

Vesting Schedule. In general, the plan administrator determines the vesting schedule, which is specified in the relevant award agreement.

Exercise of options. The plan administrator determines the exercise price for each award, which is stated in the award agreement. The vested portion of option will expire if not exercised prior to the time as the plan administrator determines at the time of its grant. However, the maximum exercisable term is 10 years.

Transfer restrictions. Unless otherwise determined by the plan administrator and so provided in the applicable award agreement, all awards are non-transferable and shall not be subject in any manner to sale, transfer, anticipation, alienation, assignment, pledge, encumbrance or charge. All awards shall be exercised only by the grantee and amounts payable or shares issuable pursuant to any award shall be delivered only to (or for the account of) the grantee.

Dissolution, Liquidation or Change in Control. Upon our dissolution, liquidation or other events that we do not survive (or does not survive as a public company in respect of our ordinary shares), then each then outstanding option and share appreciation right shall become fully vested, all outstanding restricted shares shall fully vest free of restrictions, and all other outstanding awards granted under the YS Biopharma 2022 Plan shall become payable to the holders of such awards; provided that such acceleration provision shall not apply, unless otherwise expressly provided by the administrator, with respect to any award to the extent that the administrator has made a provision for the substitution, assumption, exchange or other continuation or settlement of the award, or the award would otherwise continue in accordance with its terms, in the circumstances. In the event of a change in control event, the administrator may, in its discretion, provide that any outstanding options or share appreciation rights shall become fully vested, that any restricted shares shall fully vest free of restrictions, and that any other outstanding awards granted under the YS Biopharma 2022 Plan shall be payable to the holders of such awards. The administrator may take such action with respect to all outstanding awards or only with respect to certain specific awards identified by the administrator.

Payment. The consideration to be paid for the shares to be issued under the YS Biopharma 2022 Plan, including the method of payment, shall be determined by the plan administrator subject to the provisions in the YS Biopharma 2022 Plan and applicable law. The tax withholding to be paid for the shares shall be determined according to the provisions in the plan and applicable law.

Duration. Subject to the termination provisions under the YS Biopharma 2022 Plan, the YS Biopharma 2022 Plan shall be valid and effective for a period of 10 years commencing on the effective date after which period no further awards will be granted, but previously granted awards (and the authority of the plan administrator with respect thereto, including the authority to amend such awards) shall remain outstanding in accordance with their applicable terms and conditions and the terms and conditions of the YS Biopharma 2022 Plan.

Termination and amendment. Unless terminated earlier, the YS Biopharma 2022 Plan has a term of 10 years, effective from the date of approval by the shareholders. Our board of directors has the authority to amend or terminate the plan. To the extent required by applicable law or any applicable listing agency or required under the Internal Revenue Code of 1986 or deemed necessary or advisable by the board of directors, the amendment this plan shall be subject to the shareholders' approval. However, no such action may adversely affect in any material way any awards previously granted without the prior written consent of the recipient.

As of the date of this Annual Report, under the YS Biopharma 2022 Plan, 6,656,582 Ordinary Shares are reserved but not issued, subject to certain adjustment.

The following table sets forth the number of options granted and outstanding under the YS Biopharma 2022 Plan as of the date of this Annual Report:

Name of Grantee	Ordinary Shares Options Awarded	Exercise Price Per Ordinary Share ($)	Grant Date	Expiration Date
Mr. Yi Zhang	1,037,549	2.1956 – 8.276	December 31, 2020	December 30, 2030
Dr. Yuan Liu	23,811	4.0724 – 8.276	December 31, 2020	December 30, 2030
Mr. Gang Li	10,965	4.0724 – 8.276	December 31, 2020	December 30, 2030
Other over 450 employees	2,399,221	4.0724 – 8.276	December 31, 2020	December 30, 2030

C. Board Practices

Board of Directors

Our board of directors consists of seven directors. Of these seven directors, four are independent. The Amended YS Biopharma Articles provide that the minimum number of directors shall be three. 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 Stanley Yi Chang, Shaojing Tong, Ajit Shetty and Viren Mehta 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 Stanley Yi Chang, Shaojing Tong and Viren Mehta. Stanley Yi Chang is the chairperson of the audit committee. Stanley Yi Chang satisfies the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC.

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 Viren Mehta, Ajit Shetty, Stanley Yi Chang and Shaojing Tong. Viren Mehta 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 Ajit Shetty, Viren Mehta, Stanley Yi Chang and Yi Zhang. Ajit Shetty 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.

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, 2023, we had 773 full-time employees. The following table sets forth the number of our full-time employees by function as of March 31, 2023.

	Number	%
Research and development	221	28.6%
General and administrative	188	24.3%
Manufacturing	315	40.8%
Sales, marketing and patient services	49	6.3%
Total	**773**	**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, 2023 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 the date of this Annual Report by:

- each person known by us to beneficially own more than 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.

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 93,058,197 Ordinary Shares issued and outstanding as of the date of this Annual Report.

	Number	%
Directors and Executive Officers[(1)]:		
Mr. Yi Zhang[(2)]	49,089,185	52.75%
Dr. Hui Shao[(3)]	2,048,780	2.20%
Mr. Bo Tan[(4)]	3,853,475	4.14%
Dr. Ajit Shetty	*	*
Dr. Viren Mehta	*	*
Dr. Stanley Yi Chang	*	*
Mr. Shaojing Tong	—	—
Dr. Zenaida Reynoso Mojares	—	—
Ms. Chunyuan Wu	*	*
Dr. Yuan Liu	—	—
Mr. Gang Li	—	—
All executive officers and directors as a group (eleven persons)	55,378,551	59.51%
Principal Shareholders:		
Mr. Yi Zhang and his affiliated entities [(2)]	49,089,185	52.75%

* Less than 1%.

(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) 38,972,000 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. Zhang; (2) 4,571,500 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) 2,435,750 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) 2,435,750 ordinary shares held by Apex Pride Global Limited, a limited liability company incorporated under the laws of British Virgin Islands and being held wholly-controlled by Ms. Xu Zhang, a daughter of Mr. Yi Zhang; and (5) 629,188 ordinary shares directly held by Mr. Yi Zhang; (6) 13,339 ordinary shares directly held by Ms. Nan Zhang; and (7) 31,658 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. See "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Concert Party Agreement" for details. The registered address of All Brilliance Investments Limited is Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands. All the registered addresses of Hopeful World Company Limited, Acton Town International and Apex Pride Global Limited are Portcullis TrustNet Chambers, P.O. Box 3444, Road Town, Tortola, British Virgin Islands.

(3) Represents (1) 1,802,780 ordinary shares held by Mountainview Investment Holdings LLC, a limited liability company incorporated under the laws of the State of Delaware and being wholly-controlled by Mr. Hui Shao; and (2) 200,000 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.

(4) The shares reported are held in the name of the Sponsor. Mr. Bo Tan is one of the three managers of the Sponsor. The managers have voting and investment discretion with respect to the ordinary shares held of record by the Sponsor. Each of the managers of the Sponsor disclaims any beneficial ownership of the securities held by the Sponsor other than to the extent of any pecuniary interest they may have therein, directly or indirectly.

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—C. Board Practices-Employment Agreements and Indemnification Agreements."

Share Incentive Plans

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

Other Related Party Transactions

	Fiscal Years Ended March 31,			
	2021	2022	2023	2023
	(RMB)	(RMB)	(RMB)	($)
Amounts due from related party:				
Yisheng Biopharma Holdings Limited (Hong Kong)				
Receivable collected on behalf of YS Group	30,088,833	2,966,777	-	-
Repayment to YS Group	-	33,055,610	-	-

In fiscal 2021, YS Biopharma lent RMB30,088,833 to Yisheng Biopharma Holdings Limited (Hong Kong) for its operating needs. In fiscal 2022, we lent another RMB2,966,777 to Yisheng Biopharma Holdings Limited (Hong Kong), and Yisheng Biopharma Holdings Limited (Hong Kong) repaid RMB33,055,610 in full to us. As of March 31, 2022, the balance of amount due from Yisheng Biopharma Holdings Limited (Hong Kong) was nil.

Concert Party Agreement

Yi Zhang and the entities controlled by Yi Zhang, including (1) An Diang Group Holdings Limited, YXRT Company Limited and All Brilliance Investments Limited; (2) Rui Mi and the entities controlled by Rui Mi, including Honeydrew Flower Field Ltd., ZM Home Limited and Hopeful World Company Limited; (3) Xu Zhang and the entities controlled by Xu Zhang, including Apex Pride Global Limited, Prosperous Sunrise Company Limited and Much Galaxy Company Limited; and (4) Nan Zhang and the entities controlled by Nan Zhang, including Spring Nanmu Islands Ltd., NNZF Company Limited and Acton Town International Limited (the "Concert Parties") entered into the Concert Party Agreement, pursuant to which, the Concert Parties agree and acknowledge that they have voted since commencement of our business, and will continue to vote, themselves or through any entity directly or indirectly controlled by them that own our equity interest, unanimously for any resolutions proposed at the board meetings and/or shareholders meeting of us, where applicable. According to the Concert Party Agreement, if the Concert Parties are unable to reach unanimous consensus, Yi Zhang is entitled to determine how to vote for and on behalf of himself and the Concert Parties. The Concert Agreement remains effective unless otherwise terminated by mutual consent of the Concert Parties.

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.

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

On March 17, 2023, our Ordinary Shares and Warrants commenced trading on Nasdaq since under the symbols "YS" and "YSBPW," respectively.

B. Plan of Distribution

Not applicable.

C. Markets

See "—A. Offering and Listing Details."

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The following are summaries of material provisions of our currently effective amended and restated memorandum and articles of association, hereinafter referred to as the Amended YS Biopharma 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.

Board of Directors

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

Ordinary Shares

Voting Rights

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 Amended YS Biopharma 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 profit 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 Amended YS Biopharma Articles.

Transfer of Ordinary Shares

Subject to the restrictions contained in the Amended YS Biopharma 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.

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 Amended YS Biopharma 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.

General Meetings of Shareholders

Shareholders' meetings may be convened by our chairperson or a majority of our board of directors. 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 Amended YS Biopharma 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 Amended YS Biopharma 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:

- increase our share capital by such sum, to be divided into shares of such amount, as the resolution will prescribe;
- consolidate and divide all or any of its share capital into shares of a larger amount than existing shares;
- 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
- 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.

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 Summit Warrant outstanding immediately prior has ceased to be a warrant with respect to Summit Public Shares and be assumed by us and converted into a YS Biopharma Warrant entitling the holder thereof to purchase such number of Ordinary Share on a one-on-one basis. Each YS 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).

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.

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 of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;

- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and

- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act.

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 of the Cayman Islands, but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted in accordance with the foregoing statutory procedures, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

Shareholders' suits. In principle, we will normally be the proper plaintiff and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands 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:

- an act which is ultra vires or illegal and is therefore incapable of ratification by the shareholders;

- an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company; and

- an action which requires a resolution with a qualified (or special) majority which has not been obtained.

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), 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 Amended YS Biopharma 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.

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 Amended YS Biopharma 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.

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 Amended YS Biopharma Articles allow our shareholders holding 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 Amended YS Biopharma 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 Amended YS Biopharma 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 Amended YS Biopharma 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 Amended YS Biopharma 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 of the Cayman Islands 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.

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 Amended YS Biopharma 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 Amended YS Biopharma 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 Amended YS Biopharma 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 Amended YS Biopharma Articles that require our company to disclose shareholder ownership above any particular ownership threshold.

C. Material Contracts

Business Combination Agreement

On September 29, 2022, YS Biopharma entered into the Business Combination Agreement with Summit, Merger Sub I and Hudson Biomedical Group. 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 YS Biopharma, and (2) the merger of the Surviving Entity with and into Hudson Biomedical Group (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 Hudson Biomedical Group surviving the Second Merger as the surviving company (the "Surviving Company") and remaining as a wholly-owned subsidiary of YS Biopharma. As a result of and upon consummation of the Business Combination, the holders of shares and/or warrants of Summit has become the holders of shares and/or warrants of YS Biopharma.

Shareholder Support Agreement

Concurrently with the execution of the Business Combination Agreement, on September 29, 2022, YS Biopharma and Summit entered into a Shareholder Support Agreement and Deed (the "Shareholder Support Agreement") with certain YS Biopharma shareholders (the "YSB Shareholders") and certain Summit Shareholders (the "SPAC Shareholders" and together with the YSB Shareholders, the "Supporting Shareholders") with respect to the shares of YS Biopharma and Summit currently owned by the Supporting Shareholders. The Shareholder Support Agreement provides that, among other things, (i) the Supporting Shareholders will appear at shareholders meetings of YS Biopharma (or Summit, as applicable) and vote in favor of, consent to or approve the Business Combination Agreement and the transactions contemplated by the Business Combination Agreement, whether at a shareholder meeting of YS Biopharma (or Summit, as applicable) or by written consent, (ii) the Supporting Shareholders will vote against (or act by written consent against) any alternative proposals or actions that would impede, interfere with, delay, postpone or adversely affect the transactions contemplated by the Business Combination Agreement, (iii) the Supporting Shareholders will consent to the termination of certain registration and shareholder rights agreements with the Company (with certain exceptions), effective at the First Merger Effective Time, (iv) YS Biopharma and the YSB Shareholders will agree to amend the Shareholders Agreement (as defined in the Business Combination Agreement), effective at the First Merger Effective Time, and (v) the Sponsor will surrender 1,446,525 Summit Class B Ordinary Shares for nil consideration immediately prior to the First Merger Effective Time and exchange all of the remaining Summit Shares held by it into YS Biopharma Ordinary Shares on a one-for-one basis at the First Merger Effective Time.

Warrant Assignment Agreement

In connection with the Business Combination, YS Biopharma entered into a warrant assignment agreement dated September 29, 2022, pursuant to which Summit will assign to YS Biopharma all of its rights, title, interests, and liabilities and obligations in and under the warrant agreement dated June 8, 2021, by and between Summit and Continental Stock Transfer & trust Company.

Facility Agreement and Royalty Deed

On March 16, 2022, we entered into a facility agreement with R-Bridge Healthcare Fund, LP to finance RMB263,928,000 for 54 months with interest at 4%. We shall repay the loan in instalments on each repayment date which refers to the fifth business day after each financial quarter date an amount equal to the relevant percentage of the aggregate outstanding principal amount of the loan as the end of the availability period.

We shall pay accrued interest on the Loan on each repayment date. As of March 31, 2023, we accrued approximately RMB23.4 ($3.4) of interest.

If we fail to pay any amount payable by it under the Facility Agreement on its due date, interest shall accrue on the unpaid sum from the due date to the date of actual payment at annual interest of 3% higher than the rate which would have applied if the unpaid sum had not become due.

Under the terms of the facility agreement, we and Agent also entered into a royalty deed, dated March 16, 2022, pursuant to which we will pay to R-Bridge, the royalties on the products of YSJA rabies vaccine (royalty products) as contingent interest in addition to the payments made to R-Bridge under the facility agreement, on the terms and subject to the conditions of the royalty deed. We are obliged to pay royalties to such agent as contingent interest for the facility based upon our annual net sales of rabies vaccines by multiplying the royalty rate below by the corresponding amount incremental net sales for that financial year.

Facility Agreements with China CITIC Bank, Industrial Bank, China Construction Bank

On May 25, 2022, we entered into a credit facility of RMB30 million with China CITIC Bank and Industrial Bank for one year to finance our working capital requirements. We drew down approximately RMB29.3 million from May 12, 2022 to July 22, 2022 with interest at 5.2%. We also entered into a letter of credit facility with China CITIC Bank of approximately RMB5 million with an interest of 3.25% per annum.

On September 6, 2022, we entered into a credit facility of RMB50 million with China Construction Bank for one year to finance our working capital requirements. We drew down approximately RMB12.4 million from September 9, 2022 to September 28, 2022 with interest at 4%.

D. Exchange Controls

See "Item 4. Information on the Company—B. Business Overview—Regulations."

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.

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.

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 Governing in Cabinet undertakes with us

(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

(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:

(i) on or in respect of the shares, debentures or other obligations of us; or

(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.

We do not believe that we, a Cayman Islands holding company meets all of the conditions above. It is not a PRC resident enterprise for PRC tax purposes. As a holding company, its key assets are its ownership interests in its subsidiaries, and its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside 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 it pays to its security holders that are non-resident enterprises, including the holders of the ordinary shares and warrants. In addition, non-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 it is 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 YS Biopharma would be able to claim the benefits of any tax treaties between their country of tax residence and China in the event that YS 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 which directly owned such taxable assets may report to the relevant tax authority such indirect transfer. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax, and the transferee 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 United States 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 United States as of the date of this Annual Report, including the United States Internal Revenue Code of 1986, as amended, (the "Code"), existing and proposed United States Treasury Regulations promulgated thereunder, judicial authority, published administrative positions of the United States 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 United States 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 United States federal estate, gift, Medicare, and alternative minimum tax or other non-income tax considerations, or any state, local or non-United States tax considerations, relating to an investment in our ordinary shares.

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 United States 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:

- banks and certain other financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- controlled foreign corporations;
- "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;
- dealers, brokers or traders in securities, commodities or foreign currencies;
- persons that use or are required to use a mark-to-market method of accounting;
- accrual method taxpayers that file applicable financial statements as described in Section 451(b) of the Code;

- certain former citizens or residents of the United States subject to Section 877 of the Code;
- entities subject to the United States anti-inversion rules;
- tax-exempt organizations and entities;
- individual retirement accounts and Roth IRAs;
- S corporations;
- PFICs or their stockholders;
- persons whose functional currency is other than the United States dollar;
- persons holding ordinary shares as part of a straddle, hedging, conversion or integrated transaction;
- persons that actually or constructively own ordinary shares representing 5% or more of our total voting power or value;
- persons who acquired ordinary shares pursuant to the exercise of an employee stock option or otherwise as compensation;
- partnerships or other pass-through entities, or persons holding ordinary shares through such entities;
- 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
- 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 United States 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:

- an individual who is a citizen or resident of the United States;
- 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;
- an estate, the income of which is subject to United States federal income taxation regardless of its source; or
- 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 United States corporations. To the extent that the amount of the distribution exceeds our current and accumulated earnings and profits (as determined under United States 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 United States 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 United States 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.

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 United States. 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 United States 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).

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. 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, 2023 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 United States 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 United States (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 United States 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.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

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.

I. Subsidiary Information

Not applicable.

J. Annual Report to Security Holders

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Credit Risk

Credit risk is controlled by the application of credit approvals, limits and monitoring procedures. We manage credit risk through in-house research and analysis of the Chinese economy and the underlying obligors and transaction structures. We identify credit risk collectively based on industry, geography and customer type. In measuring the credit risk of our sales to our customers, we mainly reflect the "probability of default" by the customer on its contractual obligations and consider the current financial position of the customer and the current and likely future exposures to the customer.

Inflation risk

Inflationary factors, such as increases in the cost of raw materials, personnel and overhead costs, could impair our operating results. To date, the inflation in China has not materially affected our results of operations. According to the National Bureau of Statistics of China, the year-over-year percent changes in the consumer price index for March 2022 and 2023 were increases of 1.5% and 0.7%, respectively. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain current levels of gross margin and operating expenses as a percentage of sales revenue if the revenues from our products do not increase with such increased costs.

Interest rate risk

Our exposure to interest rate risk primarily relates to the interest rate that our deposited cash can earn, on the other hand, interest-earning instruments carry a degree of interest rate risk. We have not been exposed to material risks due to changes in interest rates. An increase, however, may raise the cost of any debt we incur in the future.

Foreign Exchange Risk

While our reporting currency is Renminbi, almost all of our financing fund are denominated in U.S. dollar. As a result, we are exposed to foreign exchange risk as our financing fund may be affected by fluctuations in the exchange rate between the U.S. dollar and Renminbi. We have not entered into any hedging transactions in an effort to reduce our exposure to foreign exchange risk.

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, 2023 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.

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, has 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, 2023, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate ICFR. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation and fair presentation of our published consolidated financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. As required by Section 404 of the Sarbanes-Oxley Act of 2002 and related rules promulgated by the SEC, our management assessed the effectiveness of our ICFR as of March 31, 2023. In making this assessment, it used the criteria established within the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management concluded that, as of March 31, 2023, our ICFR was effective.

Changes in Internal Control over Financial Reporting

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

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Stanley Yi Chang, an independent director (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 the chairman of our audit committee, is our audit committee financial expert.

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 https:// www.ysbiopharm.com/.

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 Wei, Wei & Co., LLP, our principal external auditors, for the fiscal years indicated. We did not pay any other fees to our auditors during the periods indicated below.

	Fiscal Year Ended March 31,		
	2022	2023	
	RMB	RMB	US$
Audit fees	NA	3,083,789	$ 448,767
Audit-related fees	NA	-	$ -
Tax fees	NA	-	$ -
All other fees	NA	-	$ -
Total	NA	3,083,789	$ 448,767

Audit Fees

Audit fees are related to the audit of our consolidated financial statements and other audit or interim review services provided in connection with statutory and regulatory filings or engagements. The audit fees include the audited and unaudited financial statements included in our Registration Statements on Forms F-4 and F-1, respectively.

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

Not applicable.

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. 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 Our Ordinary Shares—As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq's corporate governance requirements; these practices may afford less protection to shareholders. If we opt to rely on such exemptions in the future, such decision might afford less protection to holders of our ordinary shares."

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.

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 YS Biopharma Co., Ltd. are included at the end of this Annual Report.

ITEM 19. EXHIBITS

Exhibit Number	Description
1.1	Amended and Restated Memorandum and Articles of Association of YS Biopharma (incorporated by reference to Exhibit 3.1 to the Registration Statement on Form F-1 (File No. 333-271221) filed by the Registrant on May 12, 2023).
2.1*	Description of Securities.
2.2	Specimen Ordinary Share Certificate (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
2.3	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.6 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
2.4	Warrant Assignment Agreement, dated as of September 29, 2022, by and among Summit, YS Biopharma and Warrant Agent (incorporated herein by reference to Exhibit 10.2 of Summit's Current Report on Form 8-K filed with the SEC on September 29, 2022).
4.1	Business Combination Agreement, dated as of September 29, 2022, by and among Summit, YS Biopharma, Merger Sub I and Hudson Biomedical Group (incorporated by reference to Exhibit 2.1 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
4.2	Plan of Merger (First Merger) (incorporated by reference to Exhibit 2.2 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
4.3	Shareholder Support Agreement and Deed, dated as of September 29, 2022, by and among Summit, YS Biopharma, certain shareholders of YS Biopharma, Sponsor, and other parties thereto (incorporated herein by reference to Exhibit 10.1 of Summit's Current Report on Form 8-K filed with the SEC on September 29, 2022).
4.4	Form of Indemnification Agreement between YS Biopharma and each executive officer of YS Biopharma (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
4.5	Acting-In-Concert Agreement dated March 3, 2021 entered into by and among the Concert Parties (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
4.6	Amended and restated YS Biopharma 2020 Share Incentive Plan (the "YS Biopharma 2022 Equity Incentive Plan"), effective as of March 16, 2023 (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
8.1*	List of Principal subsidiaries.
11.1	Code of Business Conduct and Ethics of YS Biopharma (incorporated by reference to Exhibit 99.2 to the Registration Statement on Form F-4 (File No. 333-269031) filed by the Registrant on December 28, 2022).
12.1*	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2*	Certificate of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1*	Certificate of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2*	Certificate of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1*	Consent of Wei, Wei & Co., LLP., an independent registered public accounting firm for YS Biopharma.
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.

\+ Indicatesmanagement contract or compensatory plan or arrangement.

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.

YS Biopharma Co., Ltd.

By: /s/ Yi Zhang
Name: Yi Zhang
Title: Director and Chairperson

Date: July 26, 2023

YS BIOPHARMA CO., LTD AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
YS Biopharma Co., Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of YS Biopharma Co., Ltd. (formerly, YishengBio Co., Ltd.) and Subsidiaries (the "Company") as of March 31, 2023 and 2022, 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 three-year period ended March 31, 2023, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended March 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Convenience Translation

Our audits also comprehended the translation of Renminbi amounts into United States dollar amounts and, in our opinion, such translation was 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 audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Wei, Wei & Co., LLP

Flushing, New York
July 26, 2023

We have served as the Company's auditor since 2022.

YS BIOPHARMA CO., LTD AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
ASSETS			
Current assets			
Cash	271,067,503	370,108,059	$ 53,859,752
Restricted cash	-	261,766	38,093
Accounts receivable, net	308,555,105	463,051,792	67,385,333
Advance to suppliers, net	10,648,306	6,763,326	984,229
Inventories, net	166,505,565	185,380,952	26,977,451
Prepaid expenses and other current assets	7,987,914	10,412,769	1,515,312
Total current assets	**764,764,393**	**1,035,978,664**	**150,760,170**
Non-current assets			
Property, plant and equipment, net	550,153,110	571,756,443	83,204,512
Operating lease right-of-use assets, net	14,850,283	11,132,428	1,620,040
Deferred tax assets, net	3,039,084	1,905,581	277,309
Intangible assets, net	80,717,978	78,056,792	11,359,168
Other assets, non-current	28,228,293	20,923,703	3,044,909
Total non-current assets	**676,988,748**	**683,774,947**	**99,505,938**
Total assets	**1,441,753,141**	**1,719,753,611**	**$ 250,266,108**
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' (DEFICIT)/EQUITY			
Current liabilities			
Bank loans and other borrowings - current	111,733,754	193,736,563	$ 28,193,397
Accounts payable	30,811,100	80,439,489	11,705,908
Accrued expenses and other liabilities	326,751,353	377,536,644	54,940,793
Operating lease liabilities - current	4,322,252	4,753,547	691,757
Deferred government grants - current	2,295,701	2,295,701	334,081
Total current liabilities	**475,914,160**	**658,761,944**	**95,865,936**
Non-current liabilities			
Bank loans and other borrowings – non-current	253,928,000	293,790,596	42,753,699
Operating lease liabilities - non-current	10,605,260	6,348,890	923,918
Deferred government grants - non-current	30,053,517	23,606,507	3,435,323
Warrants liability	-	8,792,389	1,279,507
Total non-current liabilities	**294,586,777**	**332,538,382**	**48,392,447**
Total liabilities	**770,500,937**	**991,300,326**	**144,258,383**
Mezzanine equity			
Series A and Series A-1 redeemable convertible preferred shares (par value US$0.000005 per share, 50,000,000 shares authorized; 21,548,589 shares issued and outstanding)	458,074,468	-	-
Series B redeemable convertible preferred shares (par value US$0.000005 per share, 100,000,000 shares authorized; 65,414,858 shares issued and outstanding)	912,146,924	-	-
Total mezzanine equity	**1,370,221,392**	**-**	**-**
Shareholders'(deficit)/equity			
Ordinary shares, par value US$0.00002 per share; 9,950,000,000 shares authorized; 61,827,883 and 93,058,197 shares issued and outstanding as of March 31, 2022 and 2023, respectively; *	7,978	12,297	1,790
Additional paid-in capital	808,502,018	2,656,891,036	386,642,466
Accumulated deficit	(1,590,567,163)	(1,874,037,965)	(272,718,245)
Accumulated other comprehensive income/(loss)	83,087,979	(54,412,083)	(7,918,286)
Total shareholders' (deficit)/equity	**(698,969,188)**	**728,453,285**	**106,007,725**
Total liabilities, mezzanine equity and shareholders' (deficit)/equity	**1,441,753,141**	**1,719,753,611**	**$ 250,266,108**

* Gives retroactive effect to reflect the reorganization in February 2021 and business combination in March 2023.

The accompanying notes are an integral part of these consolidated financial statements.

YS BIOPHARMA CO., LTD AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended March 31,			
	2021	2022	2023	2023
	(RMB)	(RMB)	(RMB)	(US$)
Revenues	**257,015,929**	**502,949,894**	**687,201,070**	**$ 100,004,521**
Cost of revenues	59,656,877	117,066,090	153,360,262	22,317,660
Gross profit	**197,359,052**	**385,883,804**	**533,840,808**	**77,686,861**
Operating expenses:				
Selling and marketing	73,485,259	185,999,704	272,927,356	39,717,589
General and administrative	155,334,386	107,620,500	81,595,277	11,874,103
Research and development	94,387,144	211,222,263	318,700,526	46,378,702
Total operating expenses	**323,206,789**	**504,842,467**	**673,223,159**	**97,970,394**
Loss from operations	**(125,847,737)**	**(118,958,663)**	**(139,382,351)**	**(20,283,533)**
Other income (expenses):				
Late fees related to income tax	(11,464,741)	-	-	-
Late fees related to taxes other than income tax	(7,261,947)	(231,231)	(3,603)	(524)
Late fees related to social security insurance	(7,701,793)	(1,852,378)	(747,609)	(108,795)
Government grants	3,530,405	23,020,413	26,072,517	3,794,187
Financial expenses, net	(29,689,927)	(2,717,433)	(30,857,673)	(4,490,544)
Fair value changes of warrant liability	-	-	21,358	3,108
Other income (expense), net	4,063,743	(327,987)	551,760	80,295
Total other (expense) income, net	**(48,524,260)**	**17,891,384**	**(4,963,250)**	**(722,273)**
Loss before income taxes	**(174,371,997)**	**(101,067,279)**	**(144,345,601)**	**(21,005,806)**
Income tax expense	**(17,454,245)**	**(4,937,122)**	**(1,133,504)**	**(164,952)**
Net loss	**(191,826,242)**	**(106,004,401)**	**(145,479,105)**	**(21,170,758)**
Accretion to redemption value of convertible redeemable preferred shares	(16,610,297)	(130,662,326)	(137,991,697)	(20,081,159)
Net loss attributable to YS Group	**(208,436,539)**	**(236,666,727)**	**(283,470,802)**	**$ (41,251,917)**
Net loss	(191,826,242)	(106,004,401)	(145,479,105)	$ (21,170,758)
Other comprehensive income (loss): foreign currency translation adjustment	22,455,217	38,864,606	(137,500,062)	(20,009,614)
Total comprehensive loss	**(169,371,025)**	**(67,139,795)**	**(282,979,167)**	**$ (41,180,372)**
Loss per share*:				
– Basic and Diluted	(3.10)	(1.71)	(1.56)	$ (0.23)
Weighted average number of ordinary shares outstanding*:				
– Basic and Diluted	61,827,883	61,827,883	93,058,197	93,058,197

* Gives retroactive effect to reflect the reorganization in February 2021 and business combination in March 2023.

The accompanying notes are an integral part of these consolidated financial statements.

YS 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, 2020	**53,220,905**	**6,797**	**276,368,115**	**(1,145,463,897)**	**21,768,156**	**(847,320,829)**
Shareholders' contribution	**8,606,978**	**1,181**	**447,681,763**	-	-	**447,682,944**
Accretion to redemption value of convertible redeemable preferred shares	-	-	-	**(16,610,297)**	-	**(16,610,297)**
Net loss	-	-	-	**(191,826,242)**	-	**(191,826,242)**
Share-based compensation	-	-	**76,756,500**	-	-	**76,756,500**
Foreign currency translation adjustment	-	-	-	-	**22,455,217**	**22,455,217**
Balance as of March 31, 2021	**61,827,883**	**7,978**	**800,806,378**	**(1,353,900,436)**	**44,223,373**	**(508,862,707)**
Accretion to redemption value of convertible redeemable preferred shares	-	-	-	(130,662,326)	-	**(130,662,326)**
Net loss	-	-	-	(106,004,401)	-	**(106,004,401)**
Share-based compensation	-	-	7,764,448	-	-	**7,764,448**
Foreign currency translation adjustment	-	-	(68,808)	-	38,864,606	**38,795,798**
Balance as of March 31, 2022	**61,827,883**	**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	21,740,862	3,007	1,636,894,077		-	**1,636,897,084**
Share-based compensation	(143,750)	(20)	3,505,021	-	-	**3,505,001**
Issuance of common stock	9,633,202	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(in RMB)	**93,058,197**	**12,297**	**2,656,891,036**	**(1,874,037,965)**	**(54,412,083)**	**728,453,285**
Balance as of March 31, 2023 (in US$)	**93,058,197**	**$ 1,790**	**$ 386,642,466**	**$ (272,718,245)**	**$ (7,918,286)**	**$ 106,007,725**

* Gives retroactive effect to reflect the reorganization in February 2021 and business combination in March 2023.

The accompanying notes are an integral part of these consolidated financial statements.

YS BIOPHARMA CO., LTD AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended March 31,			
	2021	2022	2023	2023
	(RMB)	(RMB)	(RMB)	(US$)
Cash flows from operating activities:				
Net loss	(191,826,242)	(106,004,401)	(145,479,105)	$ (21,170,758)
Adjustments to reconcile net loss to net cash used in operating activities:				
Deferred income taxes	17,454,245	4,937,120	1,133,504	164,952
Depreciation of property, plant and equipment	22,240,060	24,475,736	29,735,024	4,327,171
Amortization of intangible assets	5,665,735	6,678,233	6,952,783	1,011,800
Loss on disposal of property, plant and equipment	24,876	273,982	-	-
Share-based compensation	76,756,500	7,764,448	3,505,001	510,063
Bad debt provision of accounts receivable	6,414,634	5,084,925	10,750,948	1,564,525
Write-down (reversal) of inventories to net realizable value	1,109,400	4,393,630	(723,583)	(105,299)
Non-cash lease expense	2,233,089	3,787,628	4,423,612	643,743
Fair value changes of warrant liability	-	-	(21,358)	(3,108)
Changes in operating assets and liabilities:				
Inventories	(68,728,378)	(89,459,313)	(18,151,804)	(2,641,530)
Accounts receivable	(220,734,141)	(99,137,291)	(165,247,635)	(24,047,562)
Amounts due from related parties	(3,086,330)	30,088,833	-	-
Prepaid expenses and other current assets	146,767,686	59,229,801	8,992,574	1,308,639
Accounts payable	(4,424,337)	14,427,864	49,628,389	7,222,141
Amounts due to related parties	(245,808)	-	-	-
Accrued expenses and other liabilities	140,210	(35,633,487)	43,029,496	6,261,841
Deferred government grants	(44,290)	(656,673)	(6,447,010)	(938,197)
Income taxes payable	(34,105,055)	-	-	-
Operating lease liabilities	(2,222,291)	(3,796,392)	(4,550,232)	(662,170)
Net cash used in operating activities	**(246,610,437)**	**(173,545,357)**	**(182,469,396)**	**(26,553,749)**
Cash flows from investing activities:				
Proceeds from disposal of property, plant and equipment	644,842	8,000	68,001	9,896
Purchases of property, plant and equipment	(104,883,783)	(295,314,351)	(52,758,124)	(7,677,594)
Purchases of intangible assets	-	(3,617,607)	(4,291,597)	(624,532)
Net cash used in investing activities	**(104,238,941)**	**(298,923,958)**	**(56,981,720)**	**(8,292,230)**
Cash flows from financing activities:				
Proceeds from issuance of mezzanine equity	729,412,999	-	-	-
Shareholders' contribution	1,589,236	-	-	-
Proceeds from business combination	-	-	252,457,329	36,738,701
Offering cost	-	-	(35,884,661)	(5,222,094)
Proceeds from bank loans and other borrowings	32,253,609	414,116,587	247,387,392	36,000,901
Repayment of bank loans and other borrowings	(160,407,571)	(49,558,442)	(146,510,134)	(21,320,799)
Proceeds from borrowings from related parties	299,757,219	-	-	-
Repayment of borrowings from related parties	(163,346,796)	-	-	-
Net cash provided by financing activities	**739,258,696**	**364,558,145**	**317,449,926**	**46,196,709**
Effect of foreign exchange rate on cash	(2,674)	(11,478,411)	21,303,512	3,100,180
Net increase (decrease) in cash	388,406,644	(119,389,581)	99,302,322	14,450,910
Cash at the beginning of the year	2,050,440	390,457,084	271,067,503	39,446,935
Cash at the end of the year	390,457,084	271,067,503	370,369,825	$ 53,897,845
Supplemental disclosures of cash flow information:				
Income taxes paid	34,105,055	-	-	-
Interest paid	8,124,572	2,404,357	27,289,057	$ 3,971,224
Non-cash transactions:				
Accretion to redemption value of convertible redeemable preferred shares	16,610,297	130,662,326	137,991,697	$ 20,081,159
Operating right-of-use assets recognized for related operating lease liabilities	15,048,446	1,516,478	331,218	$ 48,200
Forgiveness of amounts due to related parties	446,092,527	-	-	-
Equity transaction from warrants	-	-	(8,870,007)	$ (1,290,802)
Equity transaction from preferred shares	-	-	1,636,897,084	$ 238,208,461

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 – ORGANIZATION AND BUSINESS DESCRIPTION

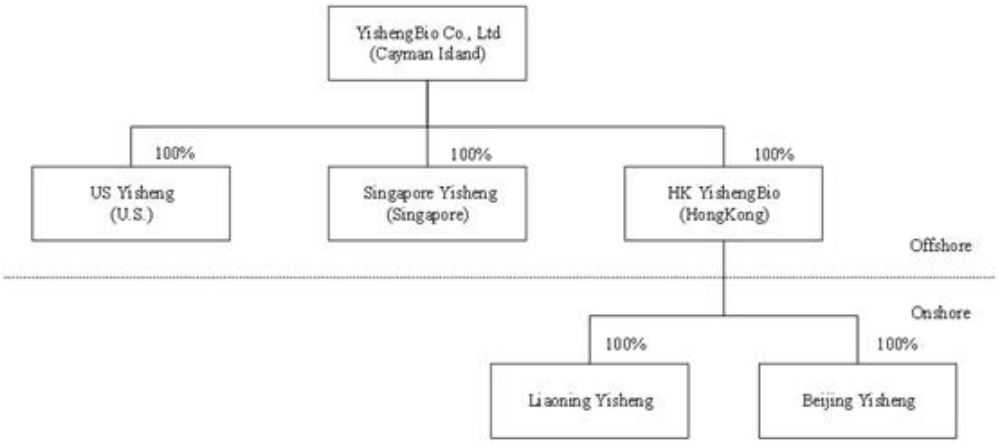
YS Biopharma Co., Ltd ("YS Biopharma"), formerly known as Yisheng Bio Co., Ltd (with the name changed March 16, 2023), was incorporated under the laws of the Cayman Islands as an exempted company with limited liability in November 2020. It owns four companies and their subsidiaries that were incorporated in the Cayman Islands, United States of America ("US"), Singapore, Hong Kong and the People's Republic of China ("China" or the "PRC") (collectively, the "Company" or "YS Group"). YS 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 is also conducting the production and sale of YSJA™ (™) rabies vaccine, the first aluminum-free lyophilized rabies vaccine launched in China.

Business Reorganization

Prior to the business reorganization completed in February 2021, YS Group conducted its business under Yisheng Biopharma Co., Ltd ("Yisheng Biopharma"), a Cayman Islands company established in April 2010, as an offshore holding company used by its shareholders to hold and control its business operation. Before or after the reorganization, both YS Biopharma and Yisheng Biopharma are controlled by the same major shareholder, Yi Zhang, founder and chairman of YS Group and Yisheng Biopharma.

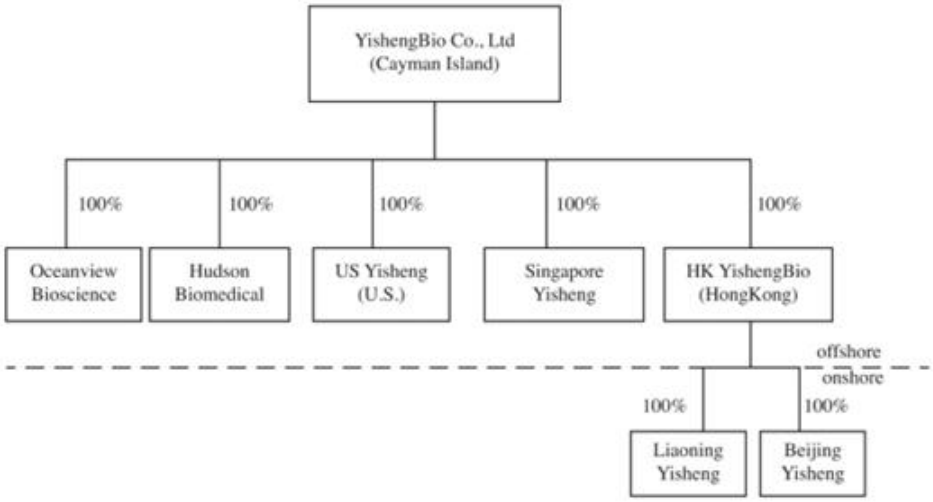
In February 2021, YS Group's business and technology segments were separated and spun-off from the parent company of Yisheng Biopharma Co., Ltd. by a series of corporate and business restructurings. In connection with such restructurings, YishengBio (Hong Kong) Holdings Limited ("HK Yisheng") and Beijing Yisheng Biotechnology Co., Ltd. ("Beijing Yisheng") were established under the laws of Hong Kong in December 2020 and the PRC in February 2021, respectively. In January 2021 and February 2021, Liaoning Yisheng Biopharma Co., Ltd. ("Liaoning Yisheng") and Beijing Yisheng became wholly-owned subsidiaries of HK Yisheng in December 2020, YS Biopharma issued shares and entered into shareholders agreement with the then shareholders of Yisheng Biopharma to substantially mirror their respective interests in Yisheng Biopharma to YS Biopharma. In January 2021, YS Biopharma acquired all the equity interests of Yisheng US Biopharma Inc. ("US Yisheng") and Yisheng Biopharma (Singapore) Pte. Ltd. ("Singapore Yisheng") from Yisheng Biopharma, both of which became wholly-owned subsidiaries of YS Biopharma. In February 2021, Beijing Yisheng acquired all the relevant assets and business from a Beijing subsidiary of Yisheng Biopharma. The restructuring was completed in February 2021. After the reorganization, there is no equity relationship, no business activities and no business relevance or competition between Yisheng Biopharma and YS Biopharma, and both are controlled by the same shareholder, Yi Zhang.

After the reorganization completed in February 2021, YS Group's legal entity structure was as follows:



Business Combination

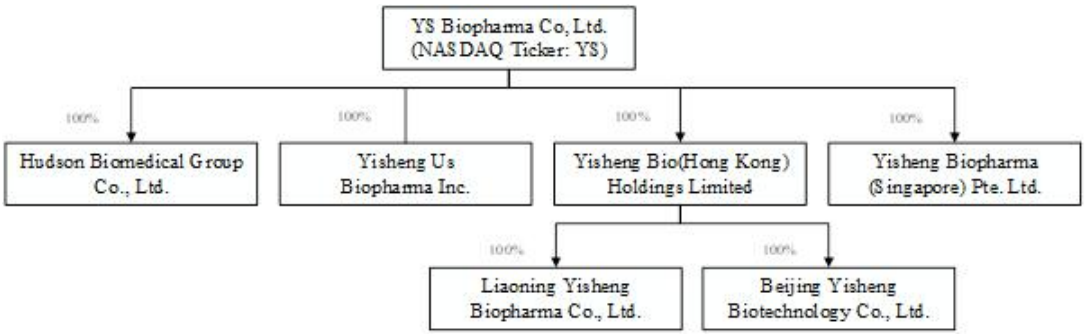
On August 15, 2022, Oceanview Bioscience Acquisition Co., Ltd. (“Oceanview Bioscience”) and Hudson Biomedical Group Co., Ltd. (“Hudson Biomedical”) were incorporated under the laws of Cayman Islands as exempted companies with limited liability. The companies were incorporated for the purpose of effecting a merger with Summit Healthcare Acquisition Corp, a Special Purpose Acquisition Company (“SPAC”). YS Group’s legal entity structure was as follows:



On September 29, 2022, YS Biopharma entered into the Business Combination Agreement with Summit Healthcare Acquisition Corp (“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 YS 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 YS Biopharma.

In accordance with the Business Combination Agreement, on the date of closing of the Mergers (“First Merger and Second Merger”), (1) each YS 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 YS Biopharma was consolidated into one Ordinary Share and one option of YS Biopharma, respectively, subject to rounding up to the nearest whole number of Ordinary Shares.

On March 16, 2023 (the “Closing Date”), YS Biopharma announced the completion of its business combination with Summit pursuant to the above Business Combination Agreement. YS Group’s current legal entity structure is as follows:



As of March 31, 2023, YS Group consists of the following legal entities:

Legal Entity	Nature of Operations	Date of Incorporation	Place of Incorporation
YS Biopharma Co., Ltd. ("YS Biopharma")***	Holding Company	November 16, 2020	Cayman Islands
YishengBio (Hong Kong) Holdings Limited ("HK Yisheng")	Holding Company	December 28, 2020	Hong Kong
Yisheng Biopharma (Singapore) Pte. Ltd. ("Singapore Yisheng")**	Research and development of vaccines and therapeutic biologics	November 28, 2009	Singapore
Yisheng US Biopharma Inc. ("US Yisheng")	Research of vaccines and therapeutic biologics	September 29, 2009	US
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

* Liaoning Yisheng was incorporated May 26, 1994, and acquired by YS Group in fiscal 2005.

** Singapore Yisheng was incorporated November 28, 2009, and acquired by YS Group in fiscal 2011

*** YS Biopharma, formerly known as Yisheng Bio Co., Ltd with the name changed on March 16, 2023.

NOTE 2 – LIQUIDITY

As reflected in the accompanying consolidated financial statements ("CFS"), the Company reported net loss of RMB191,826,242, RMB106,004,401 and RMB145,479,105 for the years ended March 31, 2021, 2022 and 2023, respectively. And the Company reported accumulated deficit of RMB1,590,567,163 and RMB1,874,037,965 as of March 31, 2022 and 2023.

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, 2023, the Company had cash of approximately RMB370.4 million (US$53.9 million). As of March 31, 2023, the Company had outstanding bank loans and other borrowings of approximately RMB487.5 million (US$70.9 million) from various financial institutions.

Currently, the Company is working to improve its liquidity and capital sources primarily through debt and equity financing. Based on the Company's current operating plan, management believes the above-mentioned measures collectively will provide sufficient liquidity for the YS Group to meet its future liquidity and capital requirement for at least 12 months from the date of this report.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These CFS and related notes of YS 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 YS 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 YS Group and its Hong Kong subsidiary, US subsidiary is the United States dollars ("US$"). The functional currency of YS Group's Singapore subsidiary is the Singapore dollars ("S$"). The functional currency of YS Group'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"). YS Group uses the RMB as its reporting currency.

The business reorganization as described in Note 1 was treated as a recapitalization of entities under common control and the accompanying CFS of YS Group give retroactive effect to this transaction.

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 CFFS include, but are not limited to, the valuation of YS Group's convertible redeemable preferred shares and ordinary shares, accrual of stock-based compensation expense, allowance for doubtful accounts 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 YS 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

YS 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 YS Group's consolidated statements of changes in shareholders' deficit. Gains and losses from foreign currency transactions are included in YS Group's consolidated statements of operations and comprehensive loss.

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 YS Group's CFS:

	As of March 31,		Years Ended March 31,		
	2022	2023	2021	2022	2023
Foreign currency	**Balance Sheet**	**Balance Sheet**	**Profit/Loss**	**Profit/Loss**	**Profit/Loss**
RMB:1US$	6.3482	6.8717	6.8282	6.4598	6.6100
RMB:1S$	4.6932	5.1760	4.9246	4.7850	4.9346

Convenience translation

Amounts in US$ are presented for the convenience of the reader and translated at US$1.00 to RMB6.8717, representing the central parity rate release of the People's Bank of China on March 31, 2023. No representation is made that the RMB amounts could have been, or converted, realized or settled into US$ at such rate.

Cash

Cash includes cash on hand and demand deposits in accounts maintained with commercial banks. YS 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. And it is included in the total cash, cash equivalents, and restricted cash in the consolidated statements of cash flows.

Accounts Receivable, net

Accounts receivable is presented net of allowance for doubtful accounts. YS Group reduces its accounts receivable by recording a bad debt allowance to account for the estimated impact of collection issues resulting from a client's inability or unwillingness to pay valid obligations to YS Group. YS Group determines the adequacy of allowance for doubtful accounts based on individual account analysis, historical collection trend, and best estimate of specific losses on individual exposures. YS Group establishes an allowance for doubtful accounts when there is objective evidence that YS Group may not be able to collect amounts due. Accounts receivable balances are written off after all collection efforts have been exhausted.

Advance to Suppliers, net

Advance to suppliers represent amounts advanced to vendors or suppliers for providing raw materials to YS Group. The suppliers usually require advance payments when YS Group orders materials and the advance will be utilized to offset YS Group's actual payment obligations. These amounts advanced are unsecured, non-interest bearing and generally short term in nature. YS Group will reduce its advance to suppliers by recording an allowance that approximates the extent of the advance that may not be realizable during the procurement process. YS Group recorded nil, nil and RMB54,870 allowance against its advance to suppliers as of March 31, 2021, 2022 and 2023.

Inventories, net

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. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

YS 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.

Adjustments are recorded to write down the cost of inventory based on the expiration date of raw materials and the estimate of future usage. Write-downs are recorded in cost of revenue in the consolidated statements of operations and comprehensive loss.

Property, Plant and Equipment, net

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, YS 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 building	6-20 years
Machinery and equipment	5-10 years
Furniture and fixtures	3-7 years
Motor vehicle	4-5 years
Leasehold improvement	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, net

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.

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 YS 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.

All research and development costs are expensed as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when YS 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

YS Group reviews long-lived assets, including definitive-lived intangible assets and property 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, YS 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 YS Group identifies an impairment, YS Group 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. YS 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 fair value less costs to sell, and no longer depreciated. YS Group did not record any impairment charges during the years ended March 31, 2023, 2022 and 2021.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially subject YS Group to concentration of credit risk consist of cash. YS Group mitigates this risk by maintaining its cash with high quality, accredited financial institutions. As of March 31, 2023, YS 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. YS 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.

YS Group's sales are made primarily to Centers for Disease Control and Prevention ("CDCs") located in China. YS Group does not have a concentration of its revenue and accounts receivable with specific customers. As of March 31, 2023 and 2022, there was no customers which accounted for more than 10% of YS Group's accounts receivable balance. During the years ended March 31, 2023, 2022 and 2021, there were no customers that accounted for more than 10% of YS Group's net revenues.

Details of percentage of YS Group's top 5 vendors accounting for total purchases are as follows:

	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%**

	Year Ended March 31, 2022		
	(RMB)	**(US$)**	
Vendor A	35,172,250	$ 5,540,508	20.9%
Vendor B	16,227,146	2,556,181	9.6%
Vendor C	9,995,189	1,574,492	5.9%
Vendor D	7,426,500	1,169,859	4.4%
Vendor E	6,621,300	1,043,020	3.9%
Total	**75,442,385**	**$ 11,884,060**	**44.7%**

	Year Ended March 31, 2021		
	(RMB)	**(US$)**	
Vendor A	32,063,500	$ 4,879,324	37.9%
Vendor F	5,781,888	879,870	6.8%
Vendor G	4,862,320	739,933	5.7%
Vendor C	4,568,088	695,157	5.4%
Vendor H	3,199,200	486,844	3.8%
Total	**50,474,996**	**$ 7,681,128**	**59.6%**

Details of percentage of YS Group's top 5 vendors accounting for accounts payable are as follows:

	As of March 31, 2023		
	(RMB)	**(US$)**	
Vendor A	3,220,000	$ 468,589	4.0%
Vendor F	420	61	0.0%
Vendor H	16,118	2,346	0.0%
Total	**3,236,538**	**$ 470,996**	**4.0%**

	As of March 31, 2022		
	(RMB)	**(US$)**	
Vendor E	1,420,549	$ 223,772	4.6%
Total	**1,420,549**	**$ 223,772**	**4.6%**

YS Group's business operation has been, and may continue to be, negatively affected by the outbreak of COVID-19. While many of the restrictions on movements within China have been relaxed, there is great uncertainty around the future of the COVID - 19 outbreak and how it will impact YS Group's operations, particularly in terms of the spread of Omicron virus in China.

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.

Unless otherwise disclosed, the FV of YS Group's financial instruments including cash, accounts receivable, advances to suppliers, amounts due from related parties, prepaid expenses and other current assets, short-term bank loans and other loans, accounts payable, warrant liabilities, and accrued expenses and other current liabilities approximate their recorded values due to their short-term maturities. The FV of longer-term leases approximates their recorded values as their stated interest rates approximate the rates currently available.

YS Group's non-financial assets, such as property and equipment would be measured at FV only if they were determined to be impaired.

Social Security Insurance

Employees of YS 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 "Standing Committee") 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 YS 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 YS 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 YS 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 YS Group. As of March 31, 2023, 2022 and 2021, YS Group's recorded late fees of RMB9.9 million, RMB9.5 million and RMB29.4 million, respectively, for its liabilities related to social security insurance (see Note 11).

Leases

Under ASC Topic 842, Leases ("ASC 842"), YS Group determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, YS Group does not recognize a right-of-use ("ROU") asset or lease liability. YS Group's operating leases are recognized on its consolidated balance sheets as noncurrent assets, current liabilities and noncurrent liabilities. YS Group does not have any finance leases.

ROU assets represent YS Group's right to use an underlying asset for the lease term and lease liabilities represent YS 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 YS Group's leases typically do not provide an implicit rate, YS 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 YS 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, YS 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, YS Group records rents in administrative expenses.

Government Grants

Government grants represent primarily subsidies received from PRC governments for operating a business in their jurisdictions and in compliance with specific policies promoted by the government authorities. YS 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 YS Group, receipt of such subsidy is not contingent upon any further actions or performance of YS 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 recognized in income when the conditions are met. Other subsidies are recognized as other income upon receipt as further performance by YS Group is not required.

Government grants for research and development ("R&D") are recognized as a reduction to R&D expenses when the conditions attached to the grants are met or recognized as government grants recognized in income 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 a reduction to the related depreciation and amortization expenses in the same manner as the property, plant and equipment are depreciated.

Convertible Redeemable Preferred Shares

YS Group has two classes of preferred shares: Series A and Series B and Series A consists of Series A and Series A-1 (collectively, the "Convertible Redeemable Preferred Shares"). These Convertible Redeemable Preferred Shares are considered "probable of becoming redeemable" as one of the redemption events depends solely on the passage of time, and the shares become redeemable following the respective anniversary of the issuance date.

Since the Series A, Series A-1 and Series B Preferred Shares are redeemable at a determinable price on a determinable date, at the option of the holder, or upon occurrence of an event that depends solely on the passage of time, the Series A, they are accounted for as mezzanine equity on the consolidated balance sheets.

The mezzanine equity is carried at the higher of (1) the carrying amount after the attribution of net income of YS Group or (2) the expected redemption value. YS Group accretes the difference between the initial carrying value and the ultimate redemption price using the effective interest rate method from the issuance dates to the earliest possible redemption date.

Upon the completion of YS Group's business combination on March 16, 2023, all the outstanding Convertible Redeemable Preferred Shares were converted into Ordinary Shares. No mezzanine equity was recognized as of March 31, 2023.

Warrants

YS 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 Summit Warrant outstanding immediately prior had ceased to be a warrant with respect to Summit Public Shares and was assumed by YS Biopharma and converted into a YS 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 accounts for the 10,750,000 public warrants as equity and 6,000,000 private warrants as liabilities.

Revenue from Contracts with Customers

YS 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 YS 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 YS Group satisfies a performance obligation

YS Group is principally engaged in the research, development, manufacturing and sale of vaccines and therapeutic biologics. YS Group's revenues primarily streams from the sales of vaccines.

The core principle underlying the revenue recognition ASC 606 is that YS Group recognizes revenue to represent the transfer of vaccines to customers in an amount that reflects the consideration to which YS Group expects to be entitled in such exchange. This requires YS Group to identify contractual performance obligations and determine whether revenue should be recognized at a point in time or over time. YS 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, YS 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. YS Group sells vaccines to the customers, and it obtains control of the vaccines before customer acceptance confirmation. Therefore, YS 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 slow-moving or obsolete inventories.

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 provision for bad debts, value-added taxes 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 YS 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.

Other Income (Expenses), net

Other income (expenses) consists of miscellaneous income and expenses not directly related to YS 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 YS 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 YS Group was undergoing the construction and certification process of new manufacturing plant, YS 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, YS Group is not subject to tax on income or capital gains. In addition, upon payments of dividends by YS Group to its shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong. Under the Hong Kong tax laws, Yisheng Hong Kong 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 paid 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%.

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 YS 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.

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 YS 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.

YS 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.

YS 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 ("VAT")

Value-added taxes ("VAT") collected from customers relating to 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

YS Group operates a share option scheme to provide incentives and rewards to eligible participants who contribute to the success of YS Group's operations. 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").

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 YS 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 YS 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 immediately. This includes any award where non-vesting conditions within the control of either the YS 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 YS Group not using RMB as its functional currency.

Shareholders' Contribution

Main sources of shareholders' contribution include debt forgiveness from related parties, cash donations from shareholders and offering. YS Group recorded the forgiveness and donations as an increase in additional paid-in capital.

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 YS Group's internal organizational structure as well as information about geographical areas, business segments and major customers in the CFS for details on YS Group's business segments.

YS Group uses the management approach to determine reportable operating segments. The management approach considers the internal organization and reporting used by YS Group's chief operating decision maker ("CODM") for making decisions, allocating resources and assessing performance. YS Group's CODM has been identified as the CEO, who reviews consolidated results when making decisions about allocating resources and assessing performance of YS Group.

Based on management's assessment, YS 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 YS Group's expenses are denominated in RMB and a significant portion of YS 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 YS 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.

YS 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 YS Group's accounts, as its aggregate deposits are higher than the compensation limit, which is RMB500,000 for one bank. However, YS Group believes the risk of failure of any of these Chinese banks is remote. Bank failure is uncommon in the PRC and YS Group believes that those Chinese banks that hold YS Group's cash are financially sound based on public available information.

Concentration and political risk

Currently, YS Group involves significant operation carried out in the PRC. Accordingly, YS 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. YS 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. YS Group's results may be adversely affected by changes in governmental policies with respect to laws and regulations, anti-inflationary measures, currency conversion and remittance abroad, and rates and methods of taxation, among other things. Although YS Group has not experienced losses from these situations and believes that it is in compliance with existing laws, this may not be indicative of future results.

Interest rate risk

Fluctuations in market interest rates may negatively affect YS Group's financial condition and results of operations. YS 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. YS Group has not used any derivative financial instruments to manage YS Group's interest risk exposure.

Related Parties

A party is considered to be related to YS Group if the party directly or indirectly or through one or more intermediaries, controls, is controlled by, or is under common control with YS Group. Related parties also include principal owners of YS Group, its management, members of the immediate families of principal owners of YS Group and its management and other parties with which YS 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.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") 2016- 13, Financial Instruments — Credit Losses (Topic 326). The amendments in this Update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The amendments broaden the information that an entity must consider in developing its expected credit loss estimate for assets measured either collectively or individually. The use of forecasted information incorporates more timely information in the estimate of expected credit loss, which will be more decision useful to users of the financial statements. This ASU is effective for annual and interim periods beginning after December 15, 2019 for issuers and December 15, 2020 for non-issuers. Early adoption is permitted for all entities for annual periods beginning after December 15, 2018, and interim periods therein. In May 2019, the FASB issued ASU 2019-05, Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief. This ASU adds optional transition relief for entities to elect the fair value option for certain financial assets previously measured at amortized cost basis to increase comparability of similar financial assets. The ASUs should be applied through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective (that is, a modified retrospective approach). On November 19, 2019, the FASB issued ASU 2019- 10 to amend the effective date for ASU 2016- 13 to be fiscal years beginning after December 15, 2022 and interim periods therein. YS Group is still evaluating the impact of accounting standard of credit losses on YS Group's CFS.

In December 2019, the FASB issued ASU 2019- 12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which removes certain exceptions to the general principles in Topic 740, and improves consistent application of and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. For public business entities, the amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. For all other entities, the amendments in this update are effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. YS Group will adopt this ASU within annual reporting period of March 31, 2023 and expects that the adoption of this ASU did not have a material impact on YS Group's CFS

YS Group does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on YS Group's consolidated financial position, statements of Income and comprehensive income and cash flows.

NOTE 4 – ACCOUNTS RECEIVABLE, NET

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Trade receivables	322,170,980	487,418,616	$ 70,931,300
Allowance for doubtful accounts	(13,615,875)	(24,366,824)	(3,545,967)
Accounts receivable, net	**308,555,105**	**463,051,792**	**$ 67,385,333**

The allowance for doubtful accounts reflects YS Group's best estimate of probable losses inherent in the accounts receivable balance. YS Group estimates the allowance based on historical experience, the age of the accounts receivable balances, credit quality of YS Group's customers, current and forecasted future economic conditions, and other factors that may affect customers' ability to pay. During the years ended March 31, 2021, 2022 and 2023, no YS Group's accounts receivable had been written off.

Below is an analysis of the movements in the allowance for doubtful accounts:

	Year Ended March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Balance at beginning of the year	8,530,951	13,615,875	$ 1,981,442
Additions	5,084,924	10,750,949	1,564,525
Balance at end of the year	**13,615,875**	**24,366,824**	**$ 3,545,967**

NOTE 5 – INVENTORIES, NET

YS Group's inventories consist of the following:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Raw materials	57,926,980	50,453,180	$ 7,342,169
Work in progress	40,795,744	61,275,177	8,917,033
Finished goods	73,285,870	78,432,041	11,413,775
Allowance for slow-moving or obsolete inventories	(5,503,029)	(4,779,446)	(695,526)
Inventories, net	**166,505,565**	**185,380,952**	**$ 26,977,451**

The movements in the allowance for slow-moving or obsolete inventories are as follows:

	Year Ended March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Balance at beginning of the year	41,301,797	5,503,029	$ 800,825
Additions	4,393,629	3,670,046	534,081
Inventories written off	(40,192,397)	(4,393,629)	(639,380)
Balance at end of the year	**5,503,029**	**4,779,446**	**$ 695,526**

NOTE 6 – PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment consist of the following:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Cost			
Construction in progress	318,000,074	309,948,621	$ 45,105,086
Plant and buildings	170,206,987	178,756,490	26,013,430
Machinery and equipment	194,875,303	237,637,928	34,582,116
Electronic equipment	10,107,578	11,117,440	1,617,859
Motor vehicles	2,978,155	3,031,087	441,097
Office equipment and furniture	29,888,526	34,423,995	5,009,531
Leasehold improvements	4,390,980	5,597,019	814,503
Total Cost	**730,447,603**	**780,512,580**	**113,583,622**
Less: accumulated depreciation	(150,402,597)	(178,864,241)	(26,029,112)
Less: asset impairment	(29,891,896)	(29,891,896)	(4,349,998)
Property and equipment, net	**550,153,110**	**571,756,443**	**$ 83,204,512**

In fiscal 2014, based on an evaluation of the company's related production plan and conditions of 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.

There are no events or changes in circumstances that indicate the carrying amount of an asset may not be fully recoverable by comparing the carrying amount of the assets to the future undiscounted cash flows expected to result from the use of the assets and their eventual disposition.

NOTE 7 – PREPAID EXPENSES AND OTHER CURRENT ASSETS, NET

Prepaid expenses and other current asset, net consist of the following:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Deposits (1)	2,807,847	4,339,791	$ 631,545
Staff advances (2)	383,251	606,859	88,313
Staff's social security (3)	615,581	252,090	36,685
Value added tax recoverable (4)	3,442,733	4,249,718	618,438
Clinical trial insurance (5)	-	178,699	26,005
Other receivable (6)	854,245	901,355	131,169
Allowance (7)	(115,743)	(115,743)	(16,843)
Total	**7,987,914**	**10,412,769**	**$ 1,515,312**

(1) Deposits primarily represented deposits to Centers for Disease Control and Prevention ("CDCs") in connection with participation in the public tender process held by province-level CDCs.

(2) Staff advances primarily represented 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 represented 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 YS Group on behalf of the employees pursuant to PRC labor regulation. When YS 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. YS 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) Clinical trial insurance represented human clinical trial legal liability insurance for evaluating the safety, immunogenicity and preliminary efficacy of multiple ascending doses of PIKA recombinant protein COID-19 Vaccine in the treatment of adult patients with mild to moderate COVID-19 infection.

(6) Other receivable primarily consists of prepayment to third parties, such as freight, water and electricity, and promotion fees.

(7) The allowance reflects YS Group's best estimate of probable amounts not fully recoverable from the other receivables balance. Due to the fact that some employees resigned and lost contact, the cash paid to them in advance of their expected business travel or in connection with various expense incurred in the ordinary course of business might not be recovered.

NOTE 8 – INTANGIBLE ASSETS, NET

YS Group's intangible assets are presented below:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Cost			
Patents	79,608,000	79,608,000	$ 11,584,906
Licenses, software and laboratory information system	6,143,880	10,435,478	1,518,617
Land use rights	67,181,860	67,181,860	9,776,600
Total Cost	**152,933,740**	**157,225,338**	**22,880,123**
Less: Accumulated Amortization	(72,215,762)	(79,168,546)	(11,520,955)
Intangible Assets, net	**80,717,978**	**78,056,792**	**$ 11,359,168**

NOTE 9 – BANK LOANS AND OTHER BORROWINGS

	As of March 31,			Maturity	Interest
	2022	2023	2023	Date	Rate
	(RMB)	(RMB)	(US$)		
China Guangfa Bank Co., Ltd. - Shenyang Branch (1)	46,456,142	41,191,031	$ 5,994,300	2023/10/13-2023/12/16	5.66%
Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch (2)	64,647,870	82,964,518	12,073,361	2023/6/29-2023/12/12	5.30%
Citi Bank (3)	234,743	-	-	2022/5/1	1.00%
R-Bridge Healthcare Fund, LP (4)	394,999	-	-	2026/9/15	4.00%
China CITIC Bank Shenyang Tiexi Branch (5	-	23,596,350	3,433,845	2023/10/13-2023/11/9	5.00%
China CITIC Bank Shenyang Tiexi Branch (6	-	5,000,000	727,622	2023/5/25-2023/7/17	3.25%
China Construction Bank Shenyang Heping Branch (7	-	31,330,000	4,559,279	2023/9/8-2023/11/24	4.00%
China Construction Bank Shenyang Heping Branch (8	-	988,000	143,778	2024/1/12	3.90%
Zhongguancun Technology Leasing Co., Ltd (10)	-	8,666,664	1,261,212	2025/11/7	5.00%
Bank loans due within one year	**111,733,754**	**193,736,563**	**$ 28,193,397**		
R-Bridge Healthcare Fund, LP (4)	253,928,000	274,868,000	40,000,000	2026/9/15	4.00%
China Construction Bank Shenyang Heping Branch (9)	-	4,430,000	644,673	2024/9/16	4.00%
Zhongguancun Technology Leasing Co., Ltd (10)		14,492,596	2,109,026	2025/11/7	5.00%
Long-term bank loans	**253,928,000**	**293,790,596**	**$ 42,753,699**		
Total bank loans	**365,661,754**	**487,527,159**	**$ 70,947,096**		

(1) On September 13, 2021, YS Group entered into a credit facility of RMB100 million with China Guangfa Bank Co., Ltd. Shenyang Branch for three years to finance its working capital requirements. YS Group drew RMB41.2 million in total from October 14 2022 to January 13, 2023 with interest at 5.66%, which is due from October 13, 2023 to December 16, 2023. In June, 2023, YS Group repaid RMB31.7 million in advance.

(2) On July 12, 2021, YS Group entered into a credit facility of RMB140 million with Shanghai Pudong Development Bank Co., Ltd. Shenyang Branch for three years to finance its working capital requirements. YS Group drew down RMB83.0 million from June 30, 2022 to December 13, 2022 with interest at 5.30%, which is due from June 29, 2023 to December 12, 2023. In April and July, 2023, YS Group repaid RMB20.9 million and RMB32.4 million in advance, respectively.

(3) On May 2, 2020, YS Group borrowed RMB1,103,609 (US$166,400) with interest at 1.00% from Citi Bank. The loan was due on May 1, 2022. Before March 31, 2022, YS Group repaid approximately RMB869,000 (US$129,422). As of March 31, 2022, the balance of approximately RMB235,000 (US$36,978) was outstanding, which amount was repaid in full in May, 2022.

(4) On March 16, 2022, YS Group entered into a facility agreement with R-Bridge Healthcare Fund, LP, as agent, to finance RMB274,868,000 (US$40,000,000) for 54 months with interest at 4.00%. YS Group shall repay the loan in instalments by repaying on each Repayment Date which means the fifth business day after each financial quarter date an amount equal to the relevant percentage of the aggregate outstanding principal amount of the loan as at the end of the Availability Period as set out in the table below:

Repayment Date	Repayment Instalment
April 7, 2025	6,400,000
July 7, 2025	6,400,000
October 7, 2025	6,400,000
January 7, 2026	6,400,000
April 7, 2026	6,400,000
July 7, 2026	8,000,000
Total	**40,000,000**

Under the terms of the Facility Agreement, YS Group and Agent are also entering into a Deed, pursuant to which YS Group will pay to Agent, the Royalties on the Products as contingent interest in addition to the payments made to Agent under the Facility Agreement, on the terms and subject to the conditions of the Deed. YS Group is obliged to pay royalties to such agent as contingent interest for the facility based upon YS Group's annual net sales of rabies vaccines by multiplying the royalty rate ranging from 1.5% to 3.5% by the corresponding amount incremental net sales for that financial year.

YS Group shall pay accrued interest on the Loan on each Payment Date. As of March 31, 2023, YS Group accrued approximately RMB23.4 million (US$3.4 million) of interest.

(5) On January 13, 2023, YS Group entered into a credit facility of RMB40 million with China CITIC Bank Shenyang Tiexi Branch, due on November 29, 2023, to finance its working capital requirements. YS Group drew RMB23.6 million from January 18, 2023 to February 17, 2023 with interest at 5.00%, which is due from October 13, 2023 to November 9, 2023.

(6) On May 6, 2022, China CITIC Bank Shenyang Tiexi Branch issued one letter of credit of RMB5.0 million to YS Group with interest at 3.25%. As of March 31, 2023, YS Group had RMB4.7 million in letters of credit issued, which is due from May 19, 2023 to July 17, 2023. From May to July 2023, YS Group repaid RMB4.7 million.

(7) From September 9, 2022 to November 25, 2022, YS Group borrowed RMB31.3 million in total with interest at 4.00% from China Construction Bank Shenyang Heping Branch for one year. The loan will be due from September 8, 2023 to November 24, 2023. On June 5, 2023, YS Group repaid RMB9.7 million in advance.

(8) On January 16, 2023, YS Group borrowed RMB988,000 with interest at 3.90% from China Construction Bank Shenyang Heping Branch for one year. The loan will be due on January 12, 2024.

(9) On March 17, 2023, YS Group borrowed RMB4.4 million with interest at 4.00% from China Construction Bank Shenyang Heping Branch for 18 months. The loan will be due on September 16, 2024.

(10) On November 8, 2022, YS Group borrowed RMB26.0 million with interest at 5.00% from Zhongguancun Technology Leasing Co., Ltd for 36 months. YS 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. YS Group repaid RMB2.9 million from December 2022 to March 2023. The balance of RMB23.1 million is outstanding, of which RMB8.6 million is due within one year. From April 13 to July 17, YS Group repaid RMB2.9 million according to the arrangement.

YS Group recorded RMB32.0 million, RMB2.8 million and RMB5.8 million of interest expense for the years ended March 31, 2023, 2022 and 2021, respectively.

NOTE 10 – LEASES

A summary of YS Group's operating leases as of March 31, 2023 and 2022 is as follows:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Operating lease ROU assets	14,850,283	11,132,428	$ 1,620,040
Operating lease liabilities - current	4,322,252	4,753,547	$ 691,757
Operating lease liabilities – non-current	10,605,260	6,348,890	$ 923,918
Weighted average remaining lease term	3.4	2.5	2.5
Weighted average discount rate	4.8%	4.7%	4.7%

A summary of lease cost recognized in YS Group's CFS and supplemental cash flow information related to operating leases is as follows:

	Years Ended March 31,			
	2021	2022	2023	2023
	(RMB)	(RMB)	(RMB)	(US$)
Operating lease cost	2,643,917	4,594,967	5,002,684	$ 728,013
Cash paid for operating leases	2,601,625	4,587,894	3,349,856	$ 487,486

A summary of maturity of operating lease liabilities under the YS Group's non-cancelable operating leases as of March 31, 2023 is as follows:

Year Ended March 31,	**(RMB)**	**(US$)**
2024	5,178,993	$ 753,670
2025	5,040,835	733,564
2026	1,526,270	222,110
Total lease payments	11,746,098	1,709,344
Less: Interest	(643,661)	(93,669)
Present value of operating lease liabilities	11,102,437	$ 1,615,675

NOTE 11 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Salaries and social security insurance payable (1)	57,459,273	55,188,497	$ 8,031,273
Promotion service fee (2)	64,883,477	87,567,459	12,743,202
Taxes other than income tax	1,171,381	379,595	55,240
Late fees (3)	9,499,595	9,927,056	1,444,629
Payable for property, plant and equipment	48,774,134	47,579,463	6,923,973
CDC transportation and storage fee	35,023,095	49,976,200	7,272,756
Guarantee deposits (4)	94,528,659	108,795,884	15,832,455
Professional service fee (5)	7,758,448	5,121,970	745,372
Interest payable 6	-	6,055,245	881,186
Other payable (7)	7,653,291	6,945,275	1,010,707
Total	**326,751,353**	**377,536,644**	**$ 54,940,793**

(1) This payable includes unpaid salaries and outstanding social security insurance. During fiscal 2023, YS Group paid approximately RMB2.3 million to reduce its payable for salaries and social security insurance. During the period from April 1, 2023 to the date of this report, YS Group paid approximately RMB10.2 million to reduce this payable. Salaries and social security insurance payables consist of the following:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Salaries	49,020,045	47,390,831	$ 6,896,522
Social security insurance	7,732,161	7,179,828	1,044,840
Union Fee	707,067	617,838	89,911
Total	**57,459,273**	**55,188,497**	**$ 8,031,273**

(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 represent late fees related to corporate income tax, taxes other than income tax and social security insurance and housing reserve fund contributions due to the fact that YS Group failed to pay the income tax related to calendar year 2011 to calendar year 2013, taxes other than income tax related to calendar year 2014 to the beginning of calendar year 2021 and social security insurance related to calendar year 2015 to the beginning of calendar year 2021. As of June, 2021, YS Group has fully 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 year 2022, the late fee is incurred for unpaid social insurance.

(4) Guarantee deposits primarily represented refundable deposits paid to YS Group by external service providers as a measurement to guarantee us that 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 represented service fees from consultants and other advisors.

(6) Interest payable primarily represented interest and royalties payable to R-Bridge Healthcare Fund, LP.

(7) Other payable primarily represented employees' reimbursement and value added tax.

NOTE 12 – CONVERTIBLE REDEEMABLE PREFERRED SHARES

Before Recapitalization, YS Group had two classes of preferred shares: Series A and Series B (collectively, the "Convertible Redeemable Preferred Shares") with Series A consists of Series A and A- 1. These Convertible Redeemable Preferred Shares are classified outside of the shareholders' equity section of YS Group's consolidated balance sheets because these shares contain deemed liquidation rights that are a contingent redemption feature not solely within the control of YS Group.

Series A

On December 10, 2012, pursuant to the Series A redeemable convertible preferred share purchase agreement and shareholders agreement ("Preferred Shares Agreements"), YS Biopharma issued 21,548,589 Series A redeemable convertible preferred shares ("Series A Preferred Share") to Asia Ventures II L.P., and Beacon Bioventures Fund III Limited Partnership (renamed as "F-Prime Capital Partners Healthcare Fund III LP" on December 30, 2015), collectively with any of their respective affiliates which holds Series A Preferred Shares, at US$0.93 per share for US $20,000,000, of which 6,014,313 shares of Series A were transferred as Series A-1 on September 4, 2020.

Series A-1

On September 4, 2020, pursuant to the share purchase agreement entered into by and among Asia Ventures II L.P., ("Asia Ventures"), F-Prime Capital Partners Healthcare Fund III LP("F-Prime") and Haitong XuYu International Limited, Epiphron Capital (Hong Kong) Limited, 3W Global Investment Limited, OrbiMed New Horizons Master Fund, L.P. and HH SUM XXXVI Holdings Limited (collectively "Purchasers"), Asia Ventures and F-Prime transferred 6,014,313 Series A Preferred Shares to the Purchasers. As of March 31, 2022, 15,534,276 shares Series A and 6,014,313 shares Series A- 1 were issued and outstanding.

Series B

In January 2021, the principal amount of Convertible Notes (see Note 12) together with the accrued interest of US $20,389,315 were converted into 18,393,610 Series B Preferred Shares at US $1.1085 per share, and the convertible note holders also exercised their call option rights under the Convertible Notes and converted into 9,660,324 Series B preferred shares at US $2.0703 per share.

In January 2021, YS Group raised US $88,000,000 by issuance of 36,129,245 Series B Preferred Shares to Oceanpine Investment Fund II LP, AIHC Master Fund, 3W Global Fund, MSA Growth Fund II, L.P., Epiphron Capital (Hong Kong) Limited, Wudaokou Capital Limited and Gennex China Growth Fund.

In February 2021, YS Group raised US $3,000,000 by way of issuance of 1,231,679 Series B Preferred Shares to Superstring Capital Master Fund LP.

On March 16, 2023, YS Biopharma closed its public offering. Thus, all the convertible redeemable preferred share were converted to ordinary shares on four-to-one basis at par value US$0.00002 as the agreements.

The following table summarizes YS Group's outstanding Convertible Redeemable Preferred Shares for the three years ended March 31, 2023:

	Series A		Series A-1		Series B		Total	Total
	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Carrying Value	Carrying Value
		(RMB)		(RMB)		(RMB)	(RMB)	(US$)
As of March 31, 2020	**21,548,589**	**440,585,213**	**-**	**-**	**-**	**-**	**440,585,213**	**$ 69,403,171**
Conversion of convertible notes	-	-	-	-	18,393,610	131,425,527	**131,425,527**	**20,702,802**
Call option under convertible notes	-	-	-	-	9,660,324	131,425,290	**131,425,290**	**20,702,765**
New insurance	-	-	-	-	37,360,924	597,987,709	**597,987,709**	**94,197,995**
Shares transferred	(6,014,313)	(68,232,451)	6,014,313	68,232,451	-	-	**-**	**-**
Accretion to redemption value	-	1,758,690	-	-	-	14,851,607	**16,610,297**	**2,616,536**
Foreign currency translation adjustment	-	(29,449,559)	-	(2,567,136)	-	(558,770)	**(32,575,465)**	**(5,131,449)**
As of March 31, 2021	**15,534,276**	**344,661,893**	**6,014,313**	**65,665,315**	**65,414,858**	**875,131,363**	**1,285,458,571**	**$ 202,491,820**
Accretion to redemption value	-	57,598,340	-	5,164,090	-	67,899,896	**130,662,326**	**20,582,579**
Foreign currency translation adjustment	-	(12,696,574)	-	(2,318,596)	-	(30,884,335)	**(45,899,505)**	**(7,230,318)**
As of March 31, 2022	**15,534,276**	**389,563,659**	**6,014,313**	**68,510,809**	**65,414,858**	**912,146,924**	**1,370,221,392**	**$ 215,844,081**
Accretion to redemption value		65,904,705		5,463,610		66,623,382	**137,991,697**	**20,081,159**
Foreign currency translation adjustment		34,734,369		5,866,010		77,857,300	**118,457,680**	**795,044**
Converted to ordinary shares	(15,534,276)	(490,202,733)	(6,014,313)	(79,840,429)	(65,414,858)	(1,056,627,606)	**(1,626,670,769)**	**(236,720,284)**
As of March 31, 2023	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**

Convertible Preferred Stock Rights and Preferences

Conversion rights: Each holder of the Preferred Shares has the right, at each holder's sole discretion, to convert at any time and from time to time, all or any portion of the Preferred Shares into ordinary shares. The initial conversion ratio shall be on a one for one basis, subject to certain general anti-dilution adjustments.

The Preferred Shares will be automatically converted into ordinary shares upon (i) the closing of an initial public offering (IPO) based on the applicable then-effective conversion price or (ii) upon the date specified by written consent or agreement of the holder of the majority of the then outstanding Preferred Shares, voting together as a single class on an as-converted basis.

The initial conversion price and conversion ratio is the stated issuance price of the Preferred Shares and on a one-for-one basis, respectively. The above conversion prices are subject to adjustments in the event that YS Biopharma issues additional ordinary shares or additional deemed ordinary shares through options or convertible instruments for a consideration per share received by YS Biopharma less than the original respective conversion prices, as the case may be, in effect on the date of and immediately prior to such issue. In such event, the respective conversion price is reduced, concurrently with such issue, to a price as adjusted according to an agreed-upon formula. The above conversion prices are also subject to adjustments on a proportional basis upon other dilution events.

Voting rights: Each holder of the Preferred Share is entitled to the number of votes equal to the number of ordinary shares into which such holder's preferred shares could be converted. The holders of the Preferred Shares shall vote together with ordinary shareholders, and not as a separate class or series, on all matters put before the shareholders.

Liquidation preference: Upon any liquidation, dissolution or winding up of YS Biopharma, either voluntary or involuntary (a "Liquidation Event"), the assets of YS Biopharma available for distribution shall be distributed in the following order: (i) each Series B Holder shall be entitled to receive, prior and in preference to any distribution of any of the assets of YS Biopharma to the Series A Holders and the Ordinary Holders, an amount per Series B Preferred Share held by such Series B Holder equal to the applicable Original Series B Issue Price plus a single interest at the rate of 8% of the applicable Original Series B Issue Price on an annum basis accumulated from the Original Series B Issue Date to the date such Series B Holder actually receives such repayment, plus all declared and accrued but unpaid dividends on each such Series B Preferred Share (collectively, the "Series B Liquidation Preference"); if the assets available to be distributed among the Series B Holders shall be insufficient to permit the payment to such holders, then the assets of YS Biopharma legally available for distribution shall be all distributed to the Series B Holders that would otherwise be respectively qualified therefor and entitled thereon such Series B Liquidation Preference on a pro rata basis; (ii) after full payment of the Series B Liquidation Preference, each Series A Holder shall be entitled to receive, prior and in preference to any distribution of any of the assets of YS Biopharma to the Ordinary Holders, an amount per Series A Preferred Share held by such Series A Holder equal to the applicable Original Series A Issue Price plus a single interest at the rate of 8% of the applicable Original Series A Issue Price on an annum basis accumulated from the applicable Original Series A Issue Date to the date such Series A Holder actually receives such repayment, plus all declared and accrued but unpaid dividends on each such Series A Preferred Share (collectively, the "Series A Liquidation Preference", together with the Series B Liquidation Preference, the "Liquidation Preference"); if the assets available to be distributed among the Series A Holders shall be insufficient to permit the payment to such holders, then the assets of YS Biopharma legally available for distribution shall be all distributed to the Series A Holders that would otherwise be respectively qualified therefor and entitled thereon such Series A Liquidation Preference on a pro rata basis; (iii) if there are assets of YS Biopharma available for distribution after payment of the Liquidation Preference referred to in clauses (i) and (ii) above, the remaining assets of YS Biopharma available for distribution to the Shareholders shall be distributed ratably among the Ordinary Holders and Preferred Holders on an as-converted basis.

Dividends: No dividends, whether in cash, property, or shares of YS Biopharma or otherwise, shall be declared or paid on any other shares during any previous or current fiscal year of YS Biopharma unless and until a dividend in like or greater amount has first been declared or paid on each outstanding Preferred Share (on an as-if-converted basis). All accrued and unpaid dividends, if any shall, to the extent funds are legally available therefor and subject to YS Biopharma being able to pay its debts as they fall due and the value of YS Biopharma's assets exceeding its liabilities immediately after any payment of such dividends, be mandatorily paid upon the earlier to occur of (i) a Liquidation Event, (ii) an optional conversion of Preferred Shares, (iii) an automatic conversion of Preferred Shares and (iv) a redemption of Preferred Shares. No dividends were declared by YS Biopharma's Board of Directors to date.

Redemption right: The Preferred Shares are redeemable at the option of the holders for all or any less portion of the Preferred Shares as provided herein at any time following:

- The issuance date when YS Biopharma and its subsidiaries or any ordinary share holder has material default or breach of the Preferred Shares Agreements in terms of its representation, warranties, covenants and obligations and if such breach remains uncured for 30 days after holders of the Preferred Shares give a written request to YS Group; or

- the third (3rd) anniversary of the Original Series B Issue Date, if a Qualified IPO is not achieved; In respect of the Series A Preferred Shares held by Asia Ventures and F-Prime, provided however that during the eighteen (18) months period after January 28, 2021, Asia Ventures and F-Prime shall not exercise its redemption rights pursuant to that if YS Group is still actively preparing for a Qualified IPO; In respect of the Series A Preferred Shares held by the Series A- 1 Holders, at any time following the third (3rd) anniversary of January 28, 2021, if a Qualified IPO is not achieved; or

- When Mr. Zhang, the Chairman of YS Biopharma ceases to be employed or provide service to YS Biopharma.

Since the Series A, Series A-1 and Series B Convertible Redeemable Preferred Shares are redeemable at a determinable price on a determinable date, at the option of the holder, or upon occurrence of an event that depends solely on the passage of time, these Convertible Redeemable Preferred Shares are accounted for as mezzanine equity on the consolidated balance sheets.

The mezzanine equity is carried at the higher of (1) the carrying amount after the attribution of net income of YS Group or (2) the expected redemption value. YS Group accretes for the difference between the initial carrying value and the ultimate redemption price using the effective interest rate method (17% annual compound interest for Series A, 8% annual compound interest for Series A- 1 and Series B) from the issuance dates to the earliest possible redemption date.

On March 16, 2023, YS Biopharma Co., Ltd. (the “Company”) issued a press release that announced the completion of its business combination with Summit Healthcare Acquisition Corp, and that the ordinary shares and warrants of the Company are to begin trading on the Nasdaq Capital Market on March 17, 2023. Thus, all the convertible redeemable preferred shares were converted to the ordinary share at par value US$0.00002 on four-to-one basis.

NOTE 13 – WARRANTS

As of March 31, 2023, YS Group has 10,750,000 public warrants and 6,000,000 private warrants.

YS Group accounts for its outstanding warrants in accordance with ASC 815-40-15-7D and 7F. Management determined that the private warrants do not meet the criteria for equity treatment and must be recorded as liabilities. Accordingly, YS Group classifies the private warrants as liabilities at their FV and adjusts the private warrants to FV at each reporting period. Management has 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.

Upon the consummation of the business combination, each Summit Warrant outstanding immediately prior has ceased to be a warrant with respect to Summit Public Shares and be assumed by YS Biopharma and converted into a YS Biopharma Warrant entitling the holder thereof to purchase such number of Ordinary Share on a one-on-one basis. Each YS 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, YS Group has 10,000,000 public and 6,000,000 private warrants

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, 2023
Fair value of the underlying asset as of the Valuation Date	1.6
Strike price	11.5
Life to expiration (Years.)	4.9
Volatility	62.9%
Number of steps	100
Redemption price (per share)	0.1

As of March 31, 2023, the value of the private warrants was RMB8.7 million. The change in FV from March 31, 2022 to March 31, 2023 was RMB21,358. The table below reflects the movement of warrant liabilities for the year ended March 31, 2023:

	April 1, 2022	Additions	Change in fair value	Foreign currency translation	March 31, 2023	March 31, 2023
	(RMB)	(RMB)	(RMB)	(RMB)	(RMB)	(US$)
Private Warrants	-	8,814,592	(21,358)	(845)	8,792,389	$ 1,279,507
Total	**-**	**8,814,592**	**(21,358)**	**(845)**	**8,792,389**	**$ 1,279,507**

NOTE 14 – WARRANTS ACCOUNTED AS EQUITY-METHOD INSTRUMENTS

Upon the consummation of the Business Combination with Summit, Summit's 10,000,000 public warrants were converted into YS Biopharma warrants, and YS Group sold additional 750,000 units of public warrants.

Following the Business Combination, YS 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:

- YS Biopharma will have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of YS Biopharma Ordinary Shares equals or exceeds $18.00 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.

- YS Biopharma will also have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of $0.10 per warrant upon a minimum of 30 days' prior written notice of redemption provided that the last reported sales price of YS Biopharma Ordinary Shares equals or exceeds $10.00 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 YS Biopharma Ordinary Shares determined based on the redemption date and the fair market value of the YS 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 YS Biopharma Ordinary Shares received is capped at 0.361 YS Biopharma Ordinary Shares per warrant (subject to adjustment) irrespective of the remaining life of the warrants.

In each case, YS 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 15 – STOCK-BASED COMPENSATION

YS 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 YS Group's operations. Eligible participants of the Scheme include YS Group's directors, employees and consultants.

The 2010 Share Incentive Plan

On June 21, 2010, YS 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. YS Group's Board of Directors authorized and reserved for the issuance of up to 2,725,650 ordinary shares under the Plan for the period from 2010 to 2013, giving retroactive effect of combination in March 2023. Starting from 1 January 2014, the maximum number of shares subject to awards that may be granted during any single calendar year is equal to 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 127,500 options, giving retroactive effect of combination in March 2023, which vest based on performance conditions, were granted to various employees. The annual grant was applicable for calendar years 2015, 2016, 2017, 2018, 2019 and 2020, respectively. The options become vested 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 YS 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.

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, 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, 2021	3,253,565	29.3156
Granted during the period	-	-
Forfeited during the period	-	-
Exercised during the period	-	-
Expired during the period	-	-
As of March 31, 2022	3,253,565	29.3156
Granted during the period	-	
Forfeited during the period	-	-
Exercised during the period	-	-
Expired during the period	-	-
As of March 31, 2023	3,253,565	32.4020

The exercise prices and exercise periods, giving retroactive effect of combination in March 2023, of the share options outstanding as at the end of the reporting periods are as follows:

Year Ended 31 March 2023		
Number of options	Exercise price	Exercise period
	(RMB)	
1,533,252	13.938	2021-2031
613,369	25.8524	2021-2026
1,106,944	52.5376	2021-2026
3,253,565		

Bonus incentive plan

On January 1, 2015, YS 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, YS Group finalizes the vested ordinary shares to be issued to the employee.

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, on February 1, 2018, YS Group granted 692,500 RSUs to employees under the Plan. The weighted average grant-date FV of restricted shares units granted was $7.24, which was derived from the FV of the underlying ordinary shares. 405,000 out of the 692,500 restricted share units 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 287,500 RSUs had been vested on March 16, 2023 due to the successful closing of the public offering. YS Group recognized expenses associated with these RSUs immediately in fiscal 2023. As of March 31, 2023, all the granted options are vested, and there were no unrecognized share-based payment expenses related to unvested restricted shares.

Giving retroactive effect of combination in March 2023, on July 25, 2018, YS Group granted 270,000 units of RSUs to three independent directors. Starting from the effective date of August 1, 2018, 30,000 RSUs will be awarded to each of the three directors annually, which shall be vested in equal portion of 7,500 units per three months' Director services rendered by each director. For each of the new directors, 5,000 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 restricted share units was $1.84, which was derived from the FV of the underlying ordinary shares. As of March 31, 2023, all the granted options are vested and there were no unrecognized share-based payment expenses related to unvested restricted shares.

The 2020 Share Incentive Plan

On December 31, 2020, YS 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 YS Group. Pursuant to such plan, YS Group is entitled to grant awards to directors, employees and consultants of YS Group with rights to subscribe for up to 8,750,000 underlying ordinary shares of YS Biopharma. As of the date of this report, (1) 2,093,418 shares as RSU incentive shares have been fully vested and issued to the respective directors and employees of YS Group, and (2) 6,656,582 shares are reserved but not issued, among which, options to subscribe for 3,471,546 ordinary shares of YS Biopharma are granted to certain senior management and employees of YS Group but not exercised, giving retroactive effect of combination in March 2023.

Stock-based compensation expense included in YS Group's consolidated statements of operations and comprehensive loss is as follows:

	Years Ended March 31,			
	2021	2022	2023	2023
	(RMB)	(RMB)	(RMB)	(US$)
Research and development	4,200,464	975,171	(997,846)	$ (145,211)
General and administrative	72,501,943	6,789,277	4,502,847	655,274
Selling and marketing	54,093	-	-	-
Total stock-based compensation	**76,756,500**	**7,764,448**	**3,505,001**	**$ 510,063**

On August 15, 2022, unanimous written resolution of the board of director of YS Group accepted the notice from a former employee, for the surrender of 143,750 of issued shares with US$0.00002 each in YS Group registered in his name, giving retroactive effect of combination in March 2023.

NOTE 16—RELATED PARTY TRANSACTIONS AND BALANCES

The following companies are related parties that had balances or transactions with YS Group as of and during the fiscal years ended March 31, 2023, 2022 and 2021:

Name of related parties	Relationship with YS Group
Yisheng Biopharma Co., Ltd	An entity controlled by Yi Zhang
Yisheng Biopharma Holdings Ltd.	An entity controlled by Yi Zhang
Kaifeng Yisheng Pan-Asia Technology Co., Ltd	An entity controlled by Yi Zhang
Beijing Yisheng Xingye Technology Co., Ltd.	An entity controlled by Yi Zhang
Changchun Bailong Biotechnology Co., Ltd.	An entity controlled by Yi Zhang
Henan Yisheng Huizhong Health Services Co., Ltd.	An entity controlled by Yi Zhang
Henan Yisheng Biopharma Co., Ltd.	An entity controlled by Yi Zhang
Beijing Huaerdun Kangqi Biotechnology Co., Ltd.	An entity controlled by Yi Zhang
Liaoning Yisheng Pan-Asia	An entity controlled by Yi Zhang
Yi Zhang	Chairman of Board of Directors
Hui Shao	Chief Executive Officer
Zhongkai Shi*	Chief Medical Officer
Nan Zhang	Daughter of the Chairman
Xu Zhang	Daughter of the Chairman

* Zhongkai Shi resigned in September 2021.

Transactions with related parties

YS Group had the following transactions with related parties, all of which are interest-free during the fiscal years ended March 31, 2023, 2022 and 2021:

	Years Ended March 31,			
	2021	2022	2023	2023
	(RMB)	(RMB)	(RMB)	(US$)
Amounts due from related party:				
Yisheng Biopharma Holdings Limited (Hong Kong)				
Receivable collected on behalf of YS Group	30,088,833	2,966,777	-	-
Repayment to YS Group		33,055,610	-	-

In fiscal 2021, YS Group lent RMB30,088,833 to Yisheng Biopharma Holdings Limited (Hong Kong) for its operating needs. In fiscal 2022, YS Group lent another RMB2,966,777 to Yisheng Biopharma Holdings Limited (Hong Kong), and Yisheng Biopharma Holdings Limited (Hong Kong) repaid RMB33,055,610 in full to YS Group. As of March 31, 2022, the balance of amount due from Yisheng Biopharma Holdings Limited (Hong Kong) is RMB nil.

NOTE 17 – INCOME TAX

Cayman Islands. Under the current laws of the Cayman Islands, YS Group is not subject to tax on income or capital gains. In addition, upon payments of dividends by YS Group to its shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong. Under the Hong Kong tax laws, Yisheng Hong Kong, 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. Yisheng Singapore, 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 December 2021, 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.

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%.

The provision for income tax consisted only of deferred tax.

The following table reconciles the statutory rate to YS Group's effective tax rate:

	Years Ended March 31,		
	2021	**2022**	**2023**
PRC statutory income tax rate	25.00%	25.00%	25.00%
Effect of different tax rates in different jurisdictions	(20.56)%	(18.26)%	(36.00)%
Effect of PRC preferential tax rate	(0.77)%	4.56%	8.72%
Effect of research and development expenses deduction and others	7.8%	33.2%	25.50%
Temporary differences*	10.01%	4.88%	0.79%
Change in valuation allowance	(11.49)%	(44.47)%	(23.23)%
Effective tax rate	**9.99%**	**4.91%**	**0.78%**

* Temporary differences primarily relate to impairment of inventories, property, plant and equipment and government grants.

Net deferred tax assets as of March 31, 2023 and 2022, consist of the following key components:

	As of March 31,		
	2022	**2023**	**2023**
	(RMB)	**(RMB)**	**(US$)**
Deferred tax assets:			
Write-down of inventories to net realizable value	825,454	716,917	$ 104,329
Impairment of property, plant and building	2,031,460	1,769,405	257,492
Deferred government grants	4,852,383	3,296,223	479,681
Losses available for offsetting against future taxable profits	58,257,270	39,366,020	5,728,716
Less: valuation allowance	(58,257,270)	(39,366,020)	(5,728,716)
Total deferred tax assets, net	**7,709,297**	**5,782,545**	**841,502**
Deferred tax liabilities:			
Fair value adjustments arising from historical acquisition of subsidiaries	(4,670,213)	(3,876,964)	(564,193)
Total deferred tax liabilities	**(4,670,213)**	**(3,876,964)**	**(564,193)**
Net deferred tax asset	**3,039,084**	**1,905,581**	**$ 277,309**

In assessing the realizability of the net deferred tax assets, YS 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 asset is considered unrealizable because it is more likely than not that YS 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, 2023 and 2022 and management does not anticipate any potential future adjustments which would result in a material change to its tax positions.

NOTE 18 – DEFERRED GOVERNMENT GRANTS

Deferred government grants represent funds received from the PRC government for research and development, investment in building or improvement in YS Group's production facilities. These specific subsidies are recorded as deferred government grants upon receipt and are recognized as government grants recognized in income when the conditions are met. Other subsidies are recognized as other income upon receipt as further performance by YS Group is not required. YS Group received government grants that were deferred in the amount of RMB4.0 million and RMB3.6 million in fiscal 2023 and 2022, respectively. In addition, YS Group received RMB15.7 million and RMB20.8 million other subsidies that the government has not set any conditions and are not tied to future trends or performance of YS Group and were recognized in other income in 2023 and 2022, respectively.

Deferred government grants included the following:

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
Government grants for property, plant and equipment			
Balance at beginning of the year	21,847,340	22,030,690	$ 3,206,003
Addition	1,552,000	-	-
Recognized as income	(1,368,650)	(1,455,678)	(211,837)
Subtotal	**22,030,690**	**20,575,012**	**$ 2,994,166**
Government grants for research and development			
Balance at beginning of the year	11,158,551	10,318,528	$ 1,501,598
Addition	-	4,000,000	582,098
Recognized as income	(840,023)	(8,991,332)	(1,308,458)
Subtotal	**10,318,528**	**5,327,196**	**$ 775,238**
Total deferred government grants	**32,349,218**	**25,902,208**	**$ 3,769,404**
Less current portion	**2,295,701**	**2,295,701**	**$ 334,081**
Non-current portion	**30,053,517**	**23,606,507**	**$ 3,435,323**

Government grants for property, plant and equipment

YS Group has seven deferred government grants related to property, plant and equipment, and has fulfilled the conditions attached to all the grants. RMB1.5 million was amortized from deferred government grant into government grant recognized in income in fiscal 2023, as compared to RMB1.4 million for the fiscal year ended March 31, 2022. RMB1.5 million will be amortized in fiscal 2024 which was included in the current deferred government grant and RMB19.1 million will be amortized after 2024 which was included in the non-current portion of deferred government grants. Nil was recorded as government grant recognized in income for the fiscal year ended March 31, 2023, as compared to RMB18.5 million for the fiscal years ended March 31, 2022.

Government grants for research and development

YS Group has four deferred government grants related to various research and development projects, and fulfilled the conditions attached to three grants. RMB9.0 million was amortized from deferred government grant into government grant recognized in income in fiscal 2023, as compared to RMB0.8 million for the fiscal year ended March 31, 2022. RMB0.8 million will be amortized in fiscal 2024 which was included in the current deferred government grant and RMB4.5 million will be amortized after 2023 which was included in the non-current portion of deferred government grants. RMB0.1 million was recorded as government grant recognized in income for the year ended March 31, 2023, as compared to RMB2.0 million for the years ended March 31, 2022.

NOTE 19 – COMMITMENTS AND CONTINGENCIES

As of March 31, 2023, YS Group has the following commitments to purchase raw materials or services:

	As of March 31,	
	2023	**2023**
	(RMB)	**(US$)**
Other professional service fee	3,229,699	$ 470,000
Research and development	185,648,604	27,016,401
Purchase raw materials	15,528,566	2,259,785
Total	**204,406,869**	**$ 29,746,186**

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 that 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, YS Group has received RMB1,636,755 compensation from Hebei Defense Biological Products Supply Center, and the balance of RMB829,052 compensation may be received in fiscal 2024.

In 2019, Liaoning Yisheng filed a sales contract dispute with Chaoyang Center for Disease Control and Prevention. The Supreme People's Court of Liaoning supported the Liaoning Yisheng's claim that the defendant Chaoyang Center for Disease Control and Prevention should pay RMB416,900 for Liaoning Yisheng vaccine. To the date, YS Group received RMB380,000 from Chaoyang Center for Disease Control and Prevention, and the balance of RMB36,900 may be received in the second half of 2023.

In 2023, Liaoning Yisheng was involved in a dispute with Shenyang Haoyu Landscape Engineering Co., Ltd who claimed that Liaoning Yisheng should pay RMB278,707 for the greening construction. As the proceedings are in the early stages, there is considerable 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.

YS Group was also involved in certain other labor disputes as of March 31, 2023. As the proceedings are in the early stages or the second appeal, there is considerable 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 20 – SEGMENT INFORMATION

Based on management's assessment, YS 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.

YS Group's non-current assets are located in the PRC and other countries, such as Singapore and United States. The location of these non-current assets can be aggregated to form the reportable geographical segment.

	As of March 31,		
	2022	2023	2023
	(RMB)	(RMB)	(US$)
PRC	604,094,049	645,210,788	$ 93,893,911
Other countries/regions	26,777,039	4,602,447	$ 669,769

The non-current asset information above is based on the location of the assets and excludes financial instruments and deferred tax assets.

NOTE 21 – SUBSEQUENT EVENTS

YS Group performed an evaluation of events and transactions for potential recognition or disclosure through the date of this report. YS Group is not aware of any material subsequent events other than those disclosed below and elsewhere in the notes to the consolidated financial statements.

On May 9, 2023, YS Biopharma (Philippines) Inc. ("Philippines Yisheng") was incorporated under the laws of Philippines as an entity owned by YS Group. Philippines Yisheng was incorporated for the purpose of research, development, producing, wholesaling and commercializing pharmaceutical products, including vaccines and other biological products.

On April 28, 2023, YS Group borrowed RMB6.7 million with interest at 5.3% from Shanghai Pudong Development Bank Co., Ltd. due on December 23, 2023.

From May 17, 2023 to June 7, 2023, YS Group borrowed RMB10.3 million with interest at 4.0% from China Construction Bank Shenyang Heping Branch for 18 months due in November and December, 2024.

From May 24, 2023 to July 18 , 2023, YS Group borrowed RMB16.4 million with interest at 5.0%, of which RMB3.6 million with interest at 4.75%, from China CITIC Bank Shenyang Tiexi Branch due from February, 2024 to May 2024.

On May 29, 2023, YS Group borrowed RMB40.0 million with interest at 4.8% from CITIC Financial Leasing Co., Ltd due on May 29, 2026.

From June 19, 2023 to July 11, 2023, YS Group borrowed RMB13.3 million with interest at 5.66% from China Guangfa Bank Co., Ltd. Shenyang Branch due on December 16, 2023.

From July 7, 2023 to July 19, 2023, YS Group borrowed RMB11.3 million with interest at 4.0% from Minsheng Bank Shenyang Huanghe Street Branch due in July, 2024.

NOTE 22 – PARENT COMPANY ONLY CONDENSED FINANCIAL INFORMATION (UNAUDITED)

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. YS Group performed a test on the restricted net assets of consolidated subsidiaries in accordance with such requirement and concluded that it was applicable to YS Group as the restricted net assets of YS Group's PRC subsidiaries exceeded 25% of the consolidated net assets of YS Group. Therefore, the condensed financial statements of the parent company are included herein.

PARENT COMPANY BALANCE SHEETS

	As of March 31,		
	2022	2023	2023
	(RMB) (Unaudited)	(RMB) (Unaudited)	(US$) (Unaudited)
ASSETS			
Current Assets			
Cash	252,611,535	3,045,660	$ 443,218
Amounts due from related parties	519,236,876	1,039,986,896	151,343,466
Total current assets	**771,848,411**	**1,043,032,556**	**151,786,684**
Non-current assets			
Long-term investments, net	146,641,652	158,734,357	23,099,722
Total non-current assets	**146,641,652**	**158,734,357**	**23,099,722**
Total Assets	**918,490,063**	**1,201,766,913**	**$ 174,886,406**
LIABILITIES AND EQUITY			
Current Liabilities			
Accrued expenses and other liabilities	244,082,464	461,105,636	$ 67,102,120
Warrants liability	-	8,792,389	1,279,507
Amounts due to related parties	3,155,395	3,415,603	497,054
Total current liabilities	247,237,859	**473,313,628**	**68,878,681**
Total Liabilities	**247,237,859**	**473,313,628**	**68,878,681**
Mezzanine equity			
Series A and A-1 redeemable convertible preferred shares (par value US$0.000005 per share, 50,000,000 shares authorized; 21,548,589 shares issued and outstanding)	458,074,468	-	-
Series B redeemable convertible preferred shares (par value US$0.000005 per share, 100,000,000 shares authorized; 65,414,858 shares issued and outstanding)	912,146,924	-	-
Total mezzanine equity	**1,370,221,392**	**-**	**-**
Shareholders' (deficit)/equity:			
Ordinary shares, par value US$0.00002 per share; 9,950,000,000 shares authorized; 61,827,883 and 93,058,197 shares issued and outstanding as of March 31, 2022 and 2023, respectively; *	7,978	12,297	1,790
Additional paid-in capital	808,502,018	2,656,891,036	386,642,466
Accumulated deficit	(1,590,567,163)	(1,874,037,965)	(272,718,245)
Accumulated other comprehensive income/(loss)	83,087,979	(54,412,083)	(7,918,286)
Total shareholders' (deficit)/equity	**(698,969,188)**	**728,453,285**	**106,007,725**
Total liabilities, mezzanine equity and shareholders' (deficit)/equity	**918,490,063**	**1,201,766,913**	**$ 174,886,406**

* Gives retroactive effect to reflect the reorganization in February 2021 and business combination in March 2023.

PARENT COMPANY STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended March 31,			
	2021	2022	2023	2023
	RMB (Unaudited)	(RMB) (Unaudited)	(RMB) (Unaudited)	(US$) (Unaudited)
Equity loss of subsidiaries	**(60,903,713)**	**(75,864,722)**	**(138,758,136)**	**$ (20,192,694)**
Operating expenses:				
Selling and marketing	54,278	-	-	-
General and administrative	104,562,058	29,178,255	7,630,726	1,110,456
Research and development	4,352,356	988,531	(887,280)	(129,121)
Total operating expenses	108,968,692	30,166,786	6,743,446	981,335
Loss from operations	**(169,872,405)**	**(106,031,508)**	**(145,501,582)**	**(21,174,029)**
Other income (expenses):				
Financial income/(expenses)	(21,953,837)	27,107	1,119	163
Fair value changes of warrant liability	-	-	21,358	3,108
Total other income/(expense), net	**(21,953,837)**	**27,107**	**22,477**	**3,271**
Net income/(loss)	**(191,826,242)**	**(106,004,401)**	**(145,479,105)**	**(21,170,758)**
Accretion to redemption value of convertible redeemable preferred shares	(16,610,297)	(130,662,326)	(137,991,697)	(20,081,159)
Net loss attributable to YS Biopharma	**(208,436,538)**	**(236,666,727)**	**(283,470,802)**	**(41,251,917)**
Net loss	**(191,826,242)**	**(106,004,401)**	**(145,479,105)**	**(21,170,758)**
Foreign currency translation gain(loss)	22,455,217	38,864,606	(137,500,062)	(20,009,614)
Total comprehensive loss	**(169,371,025)**	**(67,139,795)**	**(282,979,167)**	**$ (41,180,372)**
Loss per share*:				
– Basic and Diluted	(3.10)	(1.71)	(1.56)	$ (0.23)
Weighted average number of ordinary shares outstanding*:				
– Basic and Diluted	61,827,883	61,827,883	93,058,197	93,058,197

* Gives retroactive effect to reflect the reorganization in February 2021 and combination in March 2023.

PARENT COMPANY STATEMENTS OF CASH FLOWS

	Years Ended March 31,			
	2021	**2022**	**2023**	**2023**
	(RMB)	**(RMB)**	**(RMB)**	**(US$)**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
Net loss	(191,826,242)	(106,004,401)	(145,479,105)	$ (21,170,758)
Equity loss of subsidiaries	60,903,713	75,864,722	138,758,136	20,192,694
Share-based compensation	76,756,500	7,764,448	3,505,001	510,063
Fair value changes of warrant liability	-	-	(21,358)	(3,108)
Changes in operating assets and liabilities:				
Amounts due from related parties	(421,125,633)	(23,299,705)	(520,750,020)	(75,781,833)
Amounts due to related parties	2,906,881	(110,893)	260,208	37,867
Accrued expenses and other liabilities	77,228,629	(24,732,348)	48,377,785	7,040,148
Net cash used in operating activities	**(395,156,152)**	**(70,518,177)**	**(475,349,353)**	**(69,174,927)**
Cash flows from investing activities:				
Payment for long-term investment	(7,658,738)	(813,776)	-	-
Net cash used in investing activities	**(7,658,738)**	**(813,776)**	**-**	**-**
Cash flows from financing activities:				
Proceeds from issuance of mezzanine equity	729,412,999	-	-	-
Shareholders' contributions	1,589,236	-	-	-
Proceeds from acquisition	-	-	252,457,329	36,738,701
Offering cost			(35,884,661)	(5,222,094)
Net cash provided by financing activities	**731,002,235**	**-**	**216,572,668**	**31,516,607**
Effect of exchange rate on cash	2,109,604	(6,353,461)	9,210,810	1,340,397
Net (decrease) increase in cash	**330,296,949**	**(77,685,414)**	**(249,565,875)**	**(36,317,923)**
Cash at the beginning of the year	**-**	**330,296,949**	**252,611,535**	**36,761,141**
Cash at the end of the year	**330,296,949**	**252,611,535**	**3,045,660**	**$ 443,218**
Non-cash transactions:				
Accretion to redemption value of convertible redeemable preferred shares	16,610,297	130,662,326	(137,991,697)	$ (20,081,159)
Forgiveness from related parties	446,092,527	-	-	-
Equity transaction from warrants	-	-	(8,870,007)	$ (1,290,802)
Equity transaction from preferred shares	-	-	1,636,897,084	$ 238,208,461

Exhibit 2.1

DESCRIPTION OF SECURITIES

A summary of the material provisions governing YS Biopharma's share capital is described below. This summary is not complete and should be read together with the Amended YS Biopharma Articles, a copy of which is included elsewhere in this registration statement.

YS Biopharma is a Cayman Islands exempted company with limited liability and is governed by the Amended YS Biopharma Articles, the Cayman Islands Companies Act, and the common law of the Cayman Islands.

YS Biopharma's authorized share capital is $50,000 divided into 2,500,000,000 ordinary shares of $0.00002 par value each. All Ordinary Shares issued and outstanding were fully paid and non-assessable.

The following are summaries of material provisions of the Amended YS Biopharma Articles and the Cayman Islands Companies Act insofar as they relate to the material terms of the Ordinary Shares.

Ordinary Shares

General

Holders of Ordinary Shares have the same rights. All of the Ordinary Shares are fully paid and non-assessable. Shareholders of YS Biopharma 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 the board of directors of YS Biopharma. In addition, YS Biopharma shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by the board of directors of YS Biopharma. The Amended YS Biopharma Articles provide that the directors of YS Biopharma 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, YS Biopharma may pay a dividend out of either profit or share premium account, provided that in no circumstances may a dividend be paid if this would result in YS Biopharma 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 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 Amended YS Biopharma Articles.

Transfer of Ordinary Shares

Subject to the restrictions contained in the Amended YS Biopharma Articles, any of YS Biopharma 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 the YS Biopharma board of directors.

The YS Biopharma 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 it have a lien. The YS Biopharma board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with YS Biopharma, accompanied by the certificate for the shares to which it relates (if any) and such other evidence as the board of directors of YS Biopharma 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 the board of directors of YS Biopharma may from time to time require, is paid to YS Biopharma in respect thereof.

If the YS Biopharma directors refuse to register a transfer, they shall, within three calendar months after the date on which the instrument of transfer was lodged with YS Biopharma, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, after compliance with any notice required of the NYSE, be suspended and the register of members closed at such times and for such periods as its 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 or otherwise (other than on conversion, redemption or purchase of ordinary shares), 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 the YS Biopharma 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. If its assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that as nearly as may be, the losses shall be borne by the YS Biopharma shareholders in proportion to the par value of the Ordinary Shares held by them.

Calls on Ordinary Shares and Forfeiture of Ordinary Shares

The board of directors of YS Biopharma 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 Ordinary Shares that have been called upon and remain unpaid are, after a notice period, subject to forfeiture.

Redemption of Ordinary Shares

Subject to the provisions of the Cayman Islands Companies Act, YS Biopharma may issue shares that are to be redeemed or are liable to be redeemed at the option of the shareholder or YS Biopharma. The redemption of such shares will be effected in such manner and upon such other terms as YS Biopharma may, by either resolution of the board of directors of YS Biopharma or special resolution of shareholders, determine before the issue of the shares. YS Biopharma may also repurchase any Ordinary Shares on such terms and in such manner as have been approved by the board of directors of YS Biopharma or by an ordinary resolution of the YS Biopharma 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, the YS Biopharma directors may accept the surrender of any fully paid share for no consideration.

Variations 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 resolution passed by at least a two-thirds majority of 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 or abrogated by, inter alia, the creation or 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.

General Meetings of Shareholders

Shareholders' meetings may be convened by the chairperson of YS Biopharma a majority of YS Biopharma's board of directors. 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.

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

The board of directors of YS Biopharma will determine whether, to what extent, at what times and places and under what conditions or articles the accounts and books of YS Biopharma will be open to the inspection by YS Biopharma shareholders, and no YS Biopharma shareholder (not being a director of YS Biopharma) will otherwise have any right of inspecting any account or book or document of YS Biopharma except as required by the Cayman Islands Companies Act.

Changes in Capital

YS Biopharma may from time to time by ordinary resolution:

- increase its share capital by such sum, to be divided into shares of such amount, as the resolution will prescribe;
- consolidate and divide all or any of its share capital into shares of a larger amount than existing shares;
- 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
- 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.

YS Biopharma may by special resolution, subject to any confirmation or consent required by the Cayman Islands Companies Act, reduce its share capital or any capital redemption reserve in any manner permitted by law.

Warrants

Upon the consummation of the Business Combination, each Summit Warrant outstanding immediately prior has ceased to be a warrant with respect to Summit Public Shares and be assumed by YS Biopharma and converted into a YS Biopharma Warrant entitling the holder thereof to purchase such number of Ordinary Share on a one-on-one basis. Each YS 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).

Exempted Company

YS Biopharma is an exempted company with limited liability incorporated under the laws of Cayman Islands. The Cayman Islands Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary resident company except for the exemptions and privileges listed below:

- an exempted company (other than an exempted company holding a license to carry on business in the Cayman Islands) does not have to file an annual return of its shareholders with the Registrar of Companies of the Cayman Islands;
- an exempted company's register of members is not open to inspection;
- an exempted company does not have to hold an annual general meeting;
- an exempted company may not issue negotiable or bearer shares, but may issue shares with no par value;
- an exempted company may obtain an undertaking against the imposition of any future taxation;
- an exempted company may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- an exempted company may register as a limited duration company; and
- an exempted company may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Data Protection in the Cayman Islands — Privacy Notice

This privacy notice explains the manner in which YS Biopharma collects, processes and maintains personal data about investors of the company pursuant to the Data Protection Act, 2017 of the Cayman Islands, as amended from time to time and any regulations, codes of practice or orders promulgated pursuant thereto ("DPA").

YS Biopharma is committed to processing personal data in accordance with the DPA. In its use of personal data, the company will be characterized under the DPA as a 'data controller', whilst certain of the company's service providers, affiliates and delegates may act as 'data processors' under the DPA. These service providers may process personal information for their own lawful purposes in connection with services provided to the company.

This privacy notice puts shareholders of YS Biopharma on notice that, by virtue of making an investment in YS Biopharma, YS Biopharma and certain of service providers of YS Biopharma may collect, record, store, transfer and otherwise process personal data by which individuals may be directly or indirectly identified.

Your personal data will be processed fairly and for lawful purposes, including (a) where the processing is necessary for the company to perform a contract to which you are a party or for taking pre-contractual steps at your request (b) where the processing is necessary for compliance with any legal, tax or regulatory obligation to which the company is subject or (c) where the processing is for the purposes of legitimate interests pursued by the company or by a service provider to whom the data are disclosed. As a data controller, the YS Biopharma will only use your personal data for the purposes for which the YS Biopharma collected it. If the YS Biopharma need to use your personal data for an unrelated purpose, the YS Biopharma will contact you.

YS Biopharma anticipate that YS Biopharma will share your personal data with the company's service providers for the purposes set out in this privacy notice. YS Biopharma may also share relevant personal data where it is lawful to do so and necessary to comply with its contractual obligations or your instructions or where it is necessary or desirable to do so in connection with any regulatory reporting obligations. In exceptional circumstances, YS Biopharma will share your personal data with regulatory, prosecuting and other governmental agencies or departments, and parties to litigation (whether pending or threatened), in any country or territory including to any other person where YS Biopharma have a public or legal duty to do so (e.g. to assist with detecting and preventing fraud, tax evasion and financial crime or compliance with a court order).

Your personal data shall not be held by YS Biopharma for longer than necessary with regard to the purposes of the data processing.

YS Biopharma will not sell your personal data. Any transfer of personal data outside of the Cayman Islands shall be in accordance with the requirements of the DPA. Where necessary, the YS Biopharma will ensure that separate and appropriate legal agreements are put in place with the recipient of that data.

YS Biopharma will only transfer personal data in accordance with the requirements of the DPA, and will apply appropriate technical and organizational information security measures designed to protect against unauthorized or unlawful processing of the personal data and against the accidental loss, destruction or damage to the personal data.

If you are a natural person, this will affect you directly. If you are a corporate investor (including, for these purposes, legal arrangements such as trusts or exempted limited partnerships) that provides YS Biopharma with personal data on individuals connected to you for any reason in relation to your investment into the company, this will be relevant for those individuals and you should inform such individuals of the content.

You have certain rights under the DPA, including (a) the right to be informed as to how YS Biopharma collect and use your personal data (and this privacy notice fulfils the YS Biopharma obligation in this respect) (b) the right to obtain a copy of your personal data (c) the right to require YS Biopharma to stop direct marketing (d) the right to have inaccurate or incomplete personal data corrected (e) the right to withdraw your consent and require YS Biopharma to stop processing or restrict the processing, or not begin the processing of your personal data (f) the right to be notified of a data breach (unless the breach is unlikely to be prejudicial) (g) the right to obtain information as to any countries or territories outside the Cayman Islands to which the YS Biopharma, whether directly or indirectly, transfer, intend to transfer or wish to transfer your personal data, general measures YS Biopharma take to ensure the security of personal data and any information available to YS Biopharma as to the source of your personal data (h) the right to complain to the Office of the Ombudsman of the Cayman Islands and (i) the right to require YS Biopharma to delete your personal data in some limited circumstances.

If you consider that your personal data has not been handled correctly, or you are not satisfied with the company's responses to any requests you have made regarding the use of your personal data, you have the right to complain to the Cayman Islands' Ombudsman. The Ombudsman can be contacted by calling +1 (345) 946-6283 or by email at info@ombudsman.ky.

Exhibit 8.1

List of Principal Subsidiaries

Name of Subsidiaries	Jurisdiction of Incorporation
Hudson Biomedical Group Co., Ltd.	Cayman Islands
Yisheng US Biopharma Inc.	United States
Yisheng Biopharma (Singapore) Pte. Ltd.	Singapore
YishengBio (Hong Kong) Holdings Limited	Hong Kong
Liaoning Yisheng Biopharma Co., Ltd.	PRC
Beijing Yisheng Biotechnology Co., Ltd.	PRC
YS BIOPHARMA (PHILIPPINES) INC.	Philippines

Exhibit 12.1

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Hui Shao, certify that:

1. I have reviewed this annual report on Form 20-F of YS Biopharma Co., Ltd. (the "Company");

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

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

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

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

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

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

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

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

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

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

Date: July 26, 2023

/s/ Hui Shao

Name: Hui Shao
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Chunyuan Wu, certify that:

1. I have reviewed this annual report on Form 20-F of YS Biopharma Co., Ltd. (the "Company");

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

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

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

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

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

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

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

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

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

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

Date: July 26, 2023

/s/ Chunyuan Wu

Name: Chunyuan Wu
Title: Chief Fiancial Officer

Exhibit 13.1

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: July 26, 2023

By: /s/ Hui Shao
Name: Hui Shao
Title: Chief Executive Officer

Exhibit 13.2

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of YS Biopharma Co., Ltd. (the "Company") on Form 20-F for the fiscal year ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Chunyuan Wu, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: July 26, 2023

By: /s/ Chunyuan Wu
Name: Chunyuan Wu
Title: Chief Financial Officer

Exhibit 15.1

WEI WEI & CO., LLP
CERTIFIED PUBLIC ACCOUNTANTS

• MAIN OFFICE
133-10 39TH AVENUE
FLUSHING, NY 11354
TEL. (718) 445-6308
FAX. (718) 445-6760

• CALIFORNIA OFFICE
440 E HUNTINGTON DR.
STE 300
ARCADIA, CA 91006
TEL. (626) 282-1630
FAX. (626) 282-9726

• BEIJING OFFICE
11/F NORTH TOWER
BEIJING KERRY CENTRE
1 GUANGHUA ROAD
CHAOYANG DISTRICT
BEIJING, 100020, PRC
TEL. (86 10) 65997923
FAX. (86 10) 65999100

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-273165) of our report dated July 26, 2023, relating to the consolidated financial statements of YS Biopharma Co., Ltd. and subsidiaries as of March 31, 2023 and 2022, and for each of the years in the three-year period ended March 31, 2023, which appears in this Annual Report on Form 20-F.

/s/ Wei, Wei & Co., LLP

Flushing, New York

July 26, 2023