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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2023

Commission File Number: 001-41598

YS BIOPHARMA CO., LTD.
(Exact name of registrant as specified in its charter)

Building No. 2, 38 Yongda Road
Daxing Biomedical Industry Park
Daxing District, Beijing, PRC
Tel: 010-89202086
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

YS Biopharma Co., Ltd.

Date: May 16, 2023

By: /s/ Yi Zhang

Name: Yi Zhang

Title: Chairman and Director

EXHIBIT INDEX

Exhibit No. **Description**

Exhibit 99.1 [YS Biopharma's PIKA Rabies Vaccine Receives Phase 3 Clinical Trial Approval in Pakistan](#)



YS Biopharma's PIKA Rabies Vaccine Receives Phase 3 Clinical Trial Approval in Pakistan

GAITHERSBURG, Md., May 16, 2023 /PRNewswire/ -- YS Biopharma Co., Ltd. (NASDAQ: YS) ("YS Biopharma" or the "Company"), a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and commercializing new generations of vaccines and therapeutic biologics for infectious diseases and cancer, today announced its PIKA Rabies Vaccine has received Phase 3 clinical trial approval from the Drug Regulatory Authority of Pakistan ("DRAP"). The Phase 3 clinical trial will evaluate the safety and immunogenicity of the Company's PIKA Rabies Vaccine in preventing rabies infection.

The PIKA Rabies Vaccine is a novel vaccine powered by YS Biopharma's proprietary PIKA adjuvant technology to induce accelerated immunity and produce a higher immune response. The PIKA Rabies Vaccine has the potential to become the first accelerated three-visit one-week regimen, superior to the currently available vaccine with a five-visit one-month or three-visit three-week regimen. The Company has completed Phase 1 and Phase 2 clinical trials of its PIKA Rabies Vaccine in Singapore. Another Phase 1 trial was also conducted in China to confirm the optimum dose and regimen to be used. All three clinical trials have shown that the PIKA rabies vaccine is safe, tolerable, and immunogenic. YS Biopharma has also obtained approval to conduct Phase 3 clinical trials of the PIKA Rabies vaccine in Singapore.

The Phase 3 study is a multi-center, multi-country study set to be conducted in Singapore, the Philippines, and Pakistan in 2023. YS Biopharma anticipates conducting Phase 3 clinical trials in healthy volunteers without exposure to animal bites, with an estimated 4,500 subjects in total. The Company is also planning to conduct more advanced clinical trials in China. Pending the successful completion of Phase 3 trials, the Company intends to submit the New Drug Application or Biologics License Application for the PIKA Rabies Vaccine to regulatory authorities in China and countries in Asia and other continents.

Dr. Zenaida Mojares, Chief Medical Officer of YS Biopharma, commented, "We are delighted to receive approval from DRAP to conduct the PIKA Rabies Vaccine Phase 3 clinical trial in Pakistan. This approval marks a significant milestone in the development of our PIKA Rabies Vaccine as we continue to expand our clinical trial program globally. Our progress enables us to advance towards our mission of providing innovative and efficacious vaccines in the fight against a vaccine-preventable rabies disease, with an almost 100% case fatality rate."

About YS Biopharma

YS Biopharma is a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and commercializing new generations of vaccines and therapeutic biologics for infectious diseases and cancer. It has developed a proprietary PIKA® immunomodulating technology platform and a series of preventive and therapeutic biologics with a potential for improved Rabies, Coronavirus, Hepatitis B, Influenza, and Shingles vaccines. YS Biopharma operates in China, the United States, Singapore and the Philippines, and is led by a management team that combines rich local expertise and global experience in the bio-pharmaceutical industry. For more information, please visit investor.ysbiopharm.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical or current fact included in this press release are forward-looking statements, including but not limited to statements regarding the expected growth of YS Biopharma, the development progress of all product candidates, the progress and results of all clinical trials, YS Biopharma’s ability to source and retain talent, and the cash position of YS Biopharma following the closing of the Business Combination. Forward-looking statements may be identified by the use of words such as “estimate,” “plan,” “project,” “forecast,” “intend,” “will,” “expect,” “anticipate,” “believe,” “seek,” “target” or other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of YS Biopharma’s management and are not predictions of actual performance.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from those expressed or implied by these forward-looking statements. Although YS Biopharma believes that it has a reasonable basis for each forward-looking statement contained in this press release, YS Biopharma cautions you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain. In addition, there are risks and uncertainties described in the final prospectus relating to the proposed Business Combination, and other documents filed by YS Biopharma from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

YS Biopharma cannot assure you that the forward-looking statements in this press release will prove to be accurate. These forward-looking statements are subject to a number of risks and uncertainties, including, among others, the ability to recognize the anticipated benefits of the Business Combination, costs related to the transaction, the impact of the global COVID-19 pandemic, the risk that the transaction disrupts current plans and operations as a result of the consummation of the transaction, the outcome of any potential litigation, government or regulatory proceedings, the sales performance of the marketed vaccine product and the clinical trial development results of the product candidates of YS Biopharma, and other risks and uncertainties, including those included under the heading “Risk Factors” in the final prospectus filed with the SEC on February 8, 2023, as supplemented on February 21, 2023, and other filings with the SEC. There may be additional risks that YS Biopharma does not presently know or that YS Biopharma currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In light of the significant uncertainties in these forward-looking statements, nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. The forward-looking statements in this press release represent the views of YS Biopharma as of the date of this press release. Subsequent events and developments may cause those views to change. However, while YS Biopharma may update these forward-looking statements in the future, there is no current intention to do so, except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing the views of YS Biopharma as of any date subsequent to the date of this press release. Except as may be required by law, YS Biopharma does not undertake any duty to update these forward-looking statements.

Investor Relations Contact

Robin Yang
Partner, ICR, LLC
Tel: +1 (212) 537-4035
Email: YSBiopharma.IR@icrinc.com
