
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 October 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

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: October 31, 2023

By: /s/ Yi Zhang

Name: Yi Zhang

Title: Chairman and Director

EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|--|
| Exhibit 99.1 | YS Biopharma Announces Completion of Subject Enrollment in Pivotal Phase 3 Clinical Trial of PIKA Rabies Vaccine |

YS Biopharma Announces Completion of Subject Enrollment in Pivotal Phase 3 Clinical Trial of PIKA Rabies Vaccine

GAITHERSBURG, Md., Oct. 31, 2023 /PRNewswire/ -- YS Biopharma Co., Ltd. (NASDAQ: YS) (“YS Biopharma” or the “Company”), a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and delivering new generations of vaccines and therapeutic biologics for infectious diseases and cancer, today announced the completion of subject enrollment in its Phase 3 clinical trial (the “Phase 3 Trial” or the “Trial”) of the Company’s PIKA Rabies Vaccine. The Trial, which will assess the safety, immunogenicity, and lot-to-lot consistency of the PIKA Rabies Vaccine, includes 4,500 subjects.

Rabies has an almost 100% fatality rate upon emergence of clinical symptoms. Each year, it claims the lives of approximately 59,000 individuals in more than 150 countries. Transmission through bites from infected dogs accounts for over 95% of rabies-related fatalities, and 40% of these deaths occur in children under the age of 15. Although rabies is typically lethal without treatment, the administration of post-exposure prophylaxis can effectively prevent fatalities when initiated following possible exposure.

The PIKA Rabies Vaccine, which utilizes YS Biopharma’s proprietary PIKA adjuvant technology, is designed to produce a more robust immune response in an accelerated timespan compared to existing rabies vaccines. Previous Phase 1 and Phase 2 clinical trials of the PIKA Rabies Vaccine have demonstrated its safety and strong immunogenicity, with the PIKA Rabies Vaccine eliciting a detectable immune response in as quick as seven days. Given these results, the PIKA Rabies Vaccine has the potential to achieve best-in-class accelerated protection and meet the WHO’s goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens.

Dr. Muhammad Ahmad, the Principal Investigator at Central Park Teaching Hospital in Lahore, Pakistan, where the first and last subjects have been enrolled, commented, “We are excited that the enrollment of all 4,500 subjects for the PIKA Rabies Vaccine’s Phase 3 Trial is now complete. The Phase 3 Trial is a critical milestone in establishing the safety and efficacy of the PIKA Rabies Vaccine. The study will provide us with more pivotal data through which we can assess the vaccine’s performance on a larger scale. We hold high hopes that these findings will help establish a new standard in rabies prevention around the world, and we are proud to be taking this significant step into promising new territory.”

Dr. Ralph Villalobos, the Principal Investigator at Philippine General Hospital in Manila, Philippines, where the first subject in the Philippines was enrolled, commented, “On behalf of the other principal investigators in the Philippines, we are delighted to have completed the enrollment of this Phase 3 Trial ahead of the targeted timeline. This study will be conducted with the highest standards of safety and quality, and we are eager to proceed and generate data on the PIKA Rabies Vaccine. We are optimistic that the PIKA Rabies Vaccine will provide rapid and strong immunogenic protection against rabies, and are excited at the prospect of improving patient adherence and the chances of survivability among those exposed to rabies.”

The Phase 3 Trial is a randomized, comparator-controlled, double-blind, multi-country and multi-center study that is currently being conducted in Pakistan and the Philippines. Its primary goal is to assess the lot-to-lot consistency, immunogenicity, and safety of the PIKA Rabies Vaccine, while also seeking to demonstrate the immunologic non-inferiority and superiority of the PIKA Rabies Vaccine compared to a control vaccine. During the Trial, the PIKA Rabies Vaccine will be administered to healthy adults using a post-exposure prophylaxis schedule. Immunogenicity and consistency will be assessed using measurements of rabies virus neutralizing antibodies (“RVNA”) at day 14, while immunologic non-inferiority will be evaluated based on differences in RVNA seroconversion rates between the control vaccine and the PIKA Rabies Vaccine at day 14.

Dr. Zenaida Mojares, Chief Medical Officer of YS Biopharma, commented, “Completing subject enrollment for the Phase 3 Trial is a major advance in our PIKA Rabies Vaccine’s clinical development trajectory. We achieved positive results in the Phase 1 and Phase 2 trials conducted in China and Singapore, respectively, and we are optimistic that this Phase 3 study will reinforce and build on our existing findings. As we draw closer to delivering evidence for the lot-to-lot consistency, immunogenicity, and safety of the PIKA Rabies Vaccine, I would like to thank the Trial subjects, principal investigators, and all our collaborating partners from around the globe for participating in this pivotal program. We remain dedicated to leveraging our advanced PIKA adjuvant technology to enhance global health and well-being, and are thrilled to explore the near-term and long-term possibilities it offers.”

About YS Biopharma

YS Biopharma is a global biopharmaceutical company dedicated to discovering, developing, manufacturing, and delivering new generations of vaccines and therapeutic biologics for infectious diseases and cancer. It has developed a proprietary PIKA[®] immunomodulating technology platform and a new generation of preventive and therapeutic biologics targeting Rabies, Coronavirus, Hepatitis B, Influenza, Shingles, and other virus infections. 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 biopharmaceutical 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 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 in YS Biopharma’s 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.

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