# 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 August 2024

Commission file number: 001-41598

# LAKESHORE 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 Form 20-F or Form 40-F.

Form 20-F ⊠ Form 40-F □

# EXHIBITS

Exhibit No.	Description
99.1	Press Release - LakeShore Biopharma Announces Financial Results for Fiscal Year 2024

# SIGNATURE

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.

# LakeShore Biopharma Co., Ltd

By: /s/ Hui Shao

Name: Hui Shao Title: Director and Chief Executive Officer

Date: August 15, 2024

#### LakeShore Biopharma Announces Financial Results for Fiscal Year 2024

#### Gross margin increased to 79.5%; product pipeline continues to advance

#### Company anticipates double-digit year-over-year revenue growth and bottom line breakeven for Fiscal Year 2025

GAITHERSBURG, MD., August 15, 2024 /PRNewswire/ -- LakeShore Biopharma Co., Ltd. (Nasdaq: LSB) ("LakeShore 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 its financial results for the fiscal year ended March 31, 2024 ("Fiscal Year 2024").

Mr. Dave Chenn, Chairman and Interim Chief Executive Officer of the Company, commented, "In Fiscal Year 2024, our revenue was affected by a shortage of finished product inventory, resulting from earlier supply chain disruptions at our YSJA rabies vaccine production facilities. Despite these difficulties, we have successfully implemented operational improvements that have normalized production, and our inventory challenges are now resolved as we enter Fiscal Year 2025. We have maintained our position as a leading rabies vaccine producer in China, and continued to improve our gross margin by emphasizing operational efficiency. We also made significant advancements in our product pipeline during Fiscal Year 2024, progressing our next-generation PIKA rabies vaccine through its ongoing Phase III clinical trial and meeting significant developmental milestones for other pipeline products."

Mr. Dave Chenn continued, "Looking ahead, our Fiscal Year 2025 strategy will focus on driving revenue growth, controlling expenses, and enhancing profit margins. We are implementing a comprehensive plan that includes cost reductions, organizational restructuring, strengthened internal controls, and strategic resource allocation to key growth areas. Our goal will be to foster innovation, efficiency, stability, and sustainable profitability as we work to build value for our shareholders."

Ms. Rachel Yu, Interim Chief Financial Officer of the Company, added, "For Fiscal Year 2024, we recorded revenues of RMB573.4 million (US\$80.8 million), representing a decrease compared to Fiscal Year 2023 due to persistent supply chain issues affecting raw material availability, manufacturing processes, and overall output capacity which impacted our topline. We recorded a gross profit of RMB455.7 million (US\$64.2 million), and our gross margin increased by 1.8 percentage points to 79.5% compared to Fiscal Year 2023. With cash and cash equivalents of RMB246.6 million (US\$34.7 million), we will maintain our focus on maximizing long-term shareholder returns by refining our business strategies and leveraging new market opportunities. Looking ahead to Fiscal Year 2025, we anticipate double-digit year-over-year growth in revenues, and expect to achieve breakeven on our bottom line by the time our fiscal year concludes on March 31, 2025."

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## **Business Updates**

# YSJA<sup>TM</sup> Rabies Vaccine

LakeShore Biopharma's marketed vaccine product, YSJA<sup>TM</sup> rabies vaccine, is the first aluminum-free lyophilized rabies vaccine launched in China. Since the Company commenced production at its current GMP-compliant facilities in February 2020, and commercialization of the product in late 2020, market intake of the Company's YSJA rabies vaccine has been consistent and strong. As of March 31, 2024, LakeShore Biopharma maintained its leadership position as one of the top rabies vaccine producers in China and has sold more than 27.3 million doses of YSJA<sup>TM</sup> rabies vaccines to approximately 1,767 Chinese Center(s) for Disease Control and Prevention ("CDC") customers, which represents 61.3% of CDC customers in China since October 2020.

## **Clinical Pipeline**

LakeShore Biopharma continues to prioritize and advance its portfolio of innovative product candidates under various clinical development stages, including PIKA rabies vaccine, PIKA YS-ON-001, and PIKA YS-HBV-002.

## **PIKA Rabies Vaccine**

• In April 2024, the Company announced positive interim results from the ongoing Phase III clinical trial of its next-generation PIKA rabies vaccine in the Philippines and Pakistan. The interim results indicate that the PIKA rabies vaccine has successfully met the primary endpoints of the trial and has the potential to achieve best-in-class accelerated protection and meet the World Health Organization's goal of a one-week rabies vaccine regimen to replace the conventional three- or four-week regimens. Subject to successful completion of the Phase III clinical trial, the Company plans to submit the New Drug Applications/Biologics License Applications to relevant regulatory authorities throughout Asia, Africa, Europe, and the Americas.

#### PIKA YS-ON-001

• PIKA YS-ON-001 is designed as an immunological therapeutical agent against cancers. In 2023, the Company completed the Phase I clinical trial of PIKA YS-ON-001 in China.

#### PIKA YS-HBV-002

• In April 2024, the Company announced that its YS-HBV-002, the second generation of immunotherapeutic vaccine designed to treat patients suffering from chronic hepatitis B virus infection, had been granted clinical trial approval by the Philippine Food and Drug Administration. In light of the approval, the Company is preparing to initiate a Phase I clinical trial for YS-HBV-002 in the Philippines.

## Fiscal Year 2024 Financial Results

### **Total Revenue**

Total revenue was RMB573.4 million (US\$80.8 million) in Fiscal Year 2024, compared to RMB687.2 million in the same period of 2023, representing a decrease of 16.6%. This was primarily due to COVID-related disruptions affecting the Company's manufacturing operations and production, which reduced batch approvals and doses available for sale. This impact was partially offset by an increase in the product price of the YSJA rabies vaccine of approximately RMB2.9 per dose.

#### **Gross Profit**

Gross profit in Fiscal Year 2024 was RMB455.7 million (US\$64.2 million), representing a 79.5% gross margin, compared to RMB533.8 million, or a 77.7% gross margin, in the same period of 2023. The improvement in gross margin was primarily due to the increase in unit price of the YSJA rabies vaccine, and a decrease in unit cost resulting from lowered delivery costs and an increase in production batches.

### Selling and Marketing Expenses

Selling and marketing expenses in Fiscal Year 2024 were RMB301.3 million (US\$42.5 million), compared to RMB272.9 million in the same period of 2023. This change was primarily due to an increase in promoting and marketing service fees to continuously promote the YSJA rabies vaccine.

## **General and Administrative Expenses**

General and administrative expenses in Fiscal Year 2024 were RMB140.1 million (US\$19.7 million), compared to RMB72.9 million in the same period of 2023. This change was primarily attributable to increases in legal fees, auditing fees, directors & officers liability insurance costs, and employee benefits.

### **Research and Development Expenses**

Research and development expenses in Fiscal Year 2024 were RMB302.8 million (US\$42.7 million), compared to RMB318.7 million in the same period of 2023. The change was primarily driven by decreases in testing fees, clinical trial fees, and consulting service fees related to the development of the Company's COVID-19 vaccine, and decreases in employee benefits as a result of staffing optimizations.

#### Impairment Loss on Inventory, Property, Plant and Equipment, and Other Assets

Impairment loss on inventory, property, plant and equipment ("PP&E"), and other assets in Fiscal Year 2024 was RMB157.4 million (US\$22.2 million), compared to RMB8.7 million in the same period of 2023. The change was primarily attributable to 1) impairment loss on inventory impacted by COVID-related disruptions affecting the Company's manufacturing operations and production and raw materials used in the research and development of the Company's COVID-19 vaccine, and 2) impairment loss on PP&E related to COVID-19 vaccine equipment.

#### Net Loss

Net loss for Fiscal Year 2024 was RMB433.5 million (US\$61.1 million), compared with RMB145.5 million in the same period of 2023.

#### **Balance Sheet**

As of March 31, 2024, the Company had cash and cash equivalents of RMB246.6 million (US\$34.7 million), compared with RMB370.4 million as of March 31, 2023.



## **Business Outlook**

The Company anticipates double-digit year-over-year revenue growth and expects to achieve breakeven in Fiscal Year 2025.

The above outlook is based on information available as of the date of this press release and reflects the Company's current and preliminary expectations regarding its business situation and market conditions. The outlook is subject to changes, especially given uncertainties and situations related to market competitive dynamics and regulatory policies, etc.

### About LakeShore Biopharma

LakeShore Biopharma, previously known as 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. The Company 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 https://investor.lakeshorebio.com/.

#### **Exchange Rate Information**

This announcement contains translations of certain RMB amounts into U.S. dollars at a specified rate solely for the convenience of the reader. Unless otherwise noted, all translations from RMB to U.S. dollars are made at a rate of RMB7.095 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, 2024.

#### **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 LakeShore Biopharma, the development progress of all product candidates, the progress and results of all clinical trials, LakeShore Biopharma's ability to source and retain talent, and the cash position of LakeShore Biopharma. Forward-looking statements may be identified by the use of words such as "estimate," "plan," "project," "potential," "forecast," "intend," "will," "expect," "anticipate," "believe," "goal," "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 LakeShore Biopharma's management and are not predictions of actual performance.

LakeShore Biopharma cannot assure you the forward-looking statements in this press release will be accurate. These forward-looking statements are subject to a number of risks and uncertainties, including those included under the heading "Risk Factors" in the company's Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, and other risks described in documents subsequently filed by the company from time to time with the SEC. There may be additional risks that LakeShore Biopharma does not presently know or that LakeShore 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 LakeShore Biopharma as of the date of this press release. Subsequent events and developments may cause those views to change. However, while LakeShore Biopharma may update these forward-looking statements as representing the views of LakeShore Biopharma as of any date subsequent to the date of this press release. Except as may be required by law, LakeShore Biopharma does not undertake any duty to update these forward-looking statements.

#### **Investor Relations Contact**

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# LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES CONSOLIDATED BALANCE SHEET (AUDITED)

	2023	2024	2024
	(RMB)	(RMB)	(US\$)
ASSETS			
Current assets			
Cash	370,108,059	246,351,231	\$ 34,721,808
Restricted cash	261,766	200,000	28,189
Accounts receivable, net	463,051,792	444,161,291	62,602,014
Advance to suppliers, net	6,763,326	1,662,739	234,354
Inventories, net	185,380,952	203,422,602	28,671,262
Prepaid expenses and other current assets	10,412,769	7,370,089	1,038,772
Total current assets	1,035,978,664	903,167,952	127,296,39
Non-current assets			
Property, plant and equipment, net	571,756,443	473,348,006	66,715,710
Operating lease right-of-use assets, net	11,132,428	7,275,367	1,025,422
Deferred tax assets, net	1,905,581	23,634,189	3,331,10
Intangible assets, net	78,056,792	71,245,336	10,041,626
Other assets, non-current	20,923,703	34,356,506	4,842,355
Total non-current assets	683,774,947	609,859,404	85,956,224
Total assets	1,719,753,611	1,513,027,356	\$ 213,252,623
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LIABILITIES AND SHAREHOLDERS' (DEFICIT)/EQUITY			
Current liabilities			
Bank loans and other borrowings - current	193,736,563	318,540,732	\$ 44,896,509
Accounts payable	80,439,489	67,774,798	9,552,473
Accrued expenses and other liabilities	377,536,644	408,737,969	57,609,301
Operating lease liabilities - current	4,753,547	5,156,540	726,785
Deferred government grants - current	2,295,701	2,015,693	284,100
Total current liabilities	658,761,944	802,225,732	113,069,168
	050,701,944	002,223,752	110,007,100
Non-current liabilities			
Bank loans and other borrowings – non-current	293,790,596	98,983,780	13,951,202
Operating lease liabilities - non-current	6,348,890	1,783,593	251,38
Deferred government grants - non-current	23,606,507	20,279,945	2,858,343
Warrants liability	8,792,389	4,548,004	641,015
Total non-current liabilities	332,538,382	125,595,322	17,701,947
Total liabilities		927,821,054	130,771,115
Total habilities	991,300,326	927,821,054	130,771,113
Shareholders'(deficit)/equity			
Ordinary shares, par value US\$0.00002 per share; 9,950,000,000 shares authorized; 93,058,197			
and 190,227,959 shares issued and outstanding as of March 31, 2023 and 2024, respectively	12 207	26 105	2 (7)
	12,297	26,105	3,679
Additional paid-in capital	2,656,891,036	2,950,862,914	415,907,387
Accumulated deficit	(1,874,037,965)	(2,307,502,836)	(325,229,434
A accumulated other community loss	(54,412,083)	(58,179,881)	(8,200,124
Accumulated other comprehensive loss		505 206 202	82,481,508
Accumulated other comprehensive loss <b>Total shareholders' equity</b> <b>Total liabilities and shareholders' equity</b>	728,453,285	585,206,302	\$ 213,252,623

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# LAKESHORE BIOPHARMA CO., LTD AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (AUDITED)

	Year	Years Ended March 31,		
	2023	2024	2024	
	(RMB)	(RMB)	(US\$)	
Revenues	687,201,070	573,418,256	\$ 80,820,050	
Cost of revenues	153,360,262	117,688,301	16,587,498	
Gross profit	533,840,808	455,729,955	64,232,552	
Operating expenses:				
Selling and marketing	272,927,356	301,259,528	42,460,821	
General and administrative	72,939,790	140,086,062	19,744,336	
Impairment loss on inventory, property, plant and equipment and other assets	8,655,487	157,415,875	22,186,875	
Research and development	318,700,526	302,800,992	42,678,082	
Total operating expenses	673,223,159	901,562,457	127,070,114	
Loss from operations	(139,382,351)	(445,832,502)	(62,837,562)	
Other income (expenses):				
Late fees for taxes other than income tax	(3,603)	-	-	
Late fees for social security insurance	(747,609)	(756,201)	(106,582)	
Government grants	26,072,517	20,708,778	2,918,785	
Financial expenses, net	(30,857,673)	(44,344,808)	(6,250,149)	
Fair value changes of warrant liability	21,358	4,458,844	628,449	
Other (expense) income, net	551,760	10,572,411	1,490,121	
Total other income (expense), net	(4,963,250)	(9,360,976)	(1,319,376)	
Loss before income taxes	(144,345,601)	(455,193,478)	(64,156,938)	
Income tax (expense) benefit	(1,133,504)	21,728,607	3,062,524	
Net loss	(145,479,105)	(433,464,871)	(61,094,414)	
Accretion to redemption value of convertible redeemable preferred shares	(137,991,697)	(100,101,071)	(01,0)1,111)	
Net loss attributable to Lakeshore Group	(283,470,802)	(433,464,871)	\$ (61,094,414)	
			ф. ( <u>с1.004.414</u> )	
Net loss	(145,479,105)	(433,464,871)	\$ (61,094,414)	
Other comprehensive income (loss): foreign currency translation adjustment	(137,500,063)	(3,767,798)	(531,050)	
Total comprehensive loss	(282,979,168)	(437,232,669)	\$ (61,625,464)	
Loss per share*:				
- Basic and Diluted	(2.35)	(4.05)	\$ (0.57)	
Weighted average number of ordinary shares outstanding*:				
– Basic and Diluted	61,785,466	106,923,121	106,923,121	

\* Gives retroactive effect to the business combination in March 2023.