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Officers and Speakers
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Gregory Aurand; Noble Capital Markets
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Sid Rajeev; Fundamental Research Corp
Howard Halpern; Taglich Brothers

Presentation

Operator: Ladies and gentlemen, thank you for standing by and welcome to YS Biopharma's earnings call for the first fiscal quarter of 2024.

[Operator Instructions]

Please note that this event is being recorded.

Now I'd like to hand the conference over to your speaker host today, Ms. Alyssa Li, the company's investor relations director. Please go ahead, madam.

Alyssa Li: Thank you very much. Hello everyone, and thank you for joining us today. Welcome to YS Biopharma's first fiscal quarter 2024 earnings conference call. Today, you will hear from our President and CEO, Dr. David Shao, who will provide an overview of our operations during the past quarter. Our CFO, Ms. Brenda Wu, will then provide a closer look into our financials. After the management team has given their prepared remarks, we will open up the call for questions.

You can refer to our first fiscal quarter 2024 financial results on our IR website at investor.ysbiopharm.com. You can also access a replay of this call on our IR website when it becomes available a few hours after its conclusion.

Before we continue, I would like to refer you to our safe harbor statement in our earnings press release, which also applies to this call as we will be making forward-looking statements. Please also note that all numbers stated in the following prepared remarks by management are in RMB terms.

With that, I'm now pleased to turn the call over to Dr. David Shao, our President and CEO.

Dr. David Shao: Hello everyone, and thank you for joining us today for our first quarter fiscal year 2024 earnings conference call. In the first quarter of 2024, our top line came under pressure due primarily to inventory issues stemming from COVID-related disruptions at our YSJA rabies vaccine manufacturing facilities. While we anticipate that the impact of this inventory issue will persist for the near term, we are confident that robust demand for our product, our continued efforts to boost our manufacturing strength, our sales network and efficiency, and the eventual commercialization of our product pipeline will keep us on the path to long-term success.

Let's begin by going over the details of our results for the first quarter of fiscal year 2024. Our total revenues for the quarter was RMB 176.3 million, representing a year-over-year decline of 14.2%. Gross profit was RMB 141.6 million, representing a gross margin of 80.3%. For the first quarter, we recorded a net loss of RMB 69.5 million.

At the end of the first quarter, we had cash and cash equivalents of RMB 311.8 million, compared with RMB 370.4 million as of March 31, 2023.

Since we launched product sales of our YSJA rabies vaccine in late 2020, the market intake of the vaccine has been consistent and strong. As of June 30, 2023, we had sold more than 22.2 million doses of our YSJA rabies vaccine to approximately 1,725 CDC customers, representing over 60% of CDC customers in China.

Next, I'd like to provide some context regarding our previous manufacturing disruptions we discussed in our previous earning call last month, the impact on our top line and our plans to overcome these near-term difficulties. Toward the end of calendar year 2022, manufacturing operations at our YSJA rabies vaccine production facilities in Shenyang were disrupted due to the COVID-19 pandemic in China. This occurred as much of China was under siege from the virus. November and December 2022 marked the peak of the country's most recent wave, which extended to the beginning of calendar year 2023.

Supply chains of raw materials, as well as the overall manufacturing operations, were disrupted due to the pandemic, which weighed on our output. Since production of the vaccine involved multiple months of lead time from raw material to finished product, the disruption caused a lingering effect, limited batch production and approval, and has impacted the number of finished doses available for sale during the second half of calendar year 2023.

We are building up our inventory and leveraging our existing inventory in an attempt to maintain sales levels month by month, while the demand for our product continues to outweigh our inventory capacity.

Vaccine manufacturing is a months-long process from start to finish. The manufacturing process starts when the vero cell is taken from the working cell bank, restored to a normal state and moved to culture media. After several generations, the cells can be used for subsequent virus infection. The virus will reproduce after being inoculated to cultured vero cells, and will be used later in the production process.

The manufacturing process also involves centrifugation, ultrafiltration, concentration, inactivation and hydrolyzation of the virus, as well as purification, formulation of semi-finished products, filling, lyophilization and packaging steps. The production cycle of YSJA rabies vaccine is approximately five months, and the shelf life of the finished product is approximately 36 months.

After the production cycle, each completed lot of products must be inspected and approved by the relevant regulatory authorities. In China, the National Medical Products Administration, or NMPA, requires vaccine products and other biologics to be sampled, inspected, and certified after thorough quality and technical checks before each batch can be delivered to customers. This quality test is also called lot release, which could take three to four months long to complete.

Due to the long and complicated vaccine production and lot release processes, we anticipate that we will continue to feel the impact of late 2022 to early 2023's delays on our top line for the rest of fiscal year 2024, which will end on March 31, 2024.

Presently, all of our revenue is derived from sales of our YSJA rabies vaccine. As rabies remains a persistent health concern in China, demand for our vaccine remains robust, and we expect market demand to persist going forward. Despite encountering near-term difficulties in our operations, the foundation of our business remains stable and our product continues to remain in demand in the marketplace.

However, we have not used our confidence in the future as an excuse to stand idly by. Our team has taken a number of steps to ensure that we emerge from the period of difficulty as a more capable and better-prepared business.

First and foremost, we are currently taking several steps to increase our production capacity. These include securing supplies of raw materials from domestic and international suppliers and conducting technical training of our manufacturing staff. Our initiatives will aid us in overcoming our weak points and enhancing GMP compliance in our manufacturing plant.

As we enhance our production capacity and output consistency, we will better equip ourselves to meet demand for our product, and we will be better prepared to avoid inventory crunches in the event that future disruptions occur.

We are also taking steps to develop our infrastructure outside of our core facilities. Over the past year, we have built up and begun operating approximately 25 satellite warehouses outside of our central warehouse in our Shenyang facilities. These warehouses are designed to facilitate more efficient delivery of our vaccines to end users. By strengthening the core of our infrastructure, we will be able to operate more effectively in both favorable and unfavorable conditions.

Second, looking beyond our production infrastructure, we have historically placed an emphasis on establishing relationships with province- and county-level CDCs across China. These efforts have helped us to develop a robust, wide-ranging sales network spread across the country. This network spanned 30 out of 34 province-level CDCs and 1,725 CDC customers in China as of June 30, 2023. In total, these represent over 60% of CDC customers in China.

Even as we take steps to diligently manage our sales and marketing expenses, our past investments in this area have provided a solid foundation from which we can grow our business in the future. As our production capacity grows, we will be able to more efficiently boost our sales by leveraging our existing network, helping us achieve greater economies of scale, maintain price stability and foster loyalty among customers. And while our investments into our sales network already benefit our business, they are also effective as a long-term strategy. Once we bring our PIKA rabies vaccine and other product candidates to market, we will be able to leverage our strong sales network to enhance their commercialization and potentially expand our market share.

Finally, we have retooled and optimized our research and development operations to better suit our current situation and the global health environment. Last year, research and development expenses were elevated due to our efforts to expedite trials of our PIKA Adjuvant COVID-19 vaccine. We have seen the global response towards COVID-19 shift as the disease becomes endemic and so we have revised our research efforts to better align with our vision of the future and the market trend.

For fiscal year 2024, we expect that the majority of our research and development investment will be focused on our new generation of rabies vaccine, the PIKA rabies vaccine, which is entering Phase III trials this year. This product candidate has the potential to become best-in-class and to lift the standard of rabies infection care globally.

The clinical data has demonstrated the potential superiority of the PIKA rabies vaccine as compared to the conventional rabies vaccines in the marketplace. We expect the total clinical budget for Phase III clinical studies of our PIKA rabies vaccine to be lower than that of our COVID-19 vaccine trials we just completed.

We just reviewed the above three approaches to better managing our expenses and enhancing our stability that will help us ensure future success. Meanwhile, we remain optimistic about multiple driving forces which we expect will contribute to the long-term growth of our business.

First, we expect that human rabies will continue to remain a substantial public health issue in large swaths of the world. Rabies is a threat particularly in lower- and middle-income countries across Asia and Africa, where the vast majority of human rabies cases occur. As we expand our presence and grow our business, we aim to enhance our capability to deliver vaccines to the communities and individuals who need them most. This will allow us to provide a critical layer of protection against a disease that otherwise has fatal consequences. Both our existing YSJA rabies vaccine and our new-generation PIKA rabies vaccine will play important roles in this strategic expansion.

Turning to our PIKA rabies vaccine, we expect that it will eventually provide us with significant growth opportunities and advantages compared to conventional rabies vaccines in the marketplace. Our PIKA rabies vaccine is expected to accelerate the onset of immunity from 14 days to seven days and can be administered in a three-visit, one-week regimen to replace the conventional regimen involving five injections, three- or four-week-long protocols.

The product has the potential to elevate the global standard of rabies treatment, as it excels beyond existing vaccines in both seroconversion rate and regimen schedule. By helping patients attain immunity sooner, the PIKA rabies vaccine will help lower death rates and enhance the chances of survival for individuals exposed to rabies. Recognizing the substantial potential benefits of PIKA rabies vaccine in comparison to traditional rabies vaccines, our intention is to develop a premium pricing strategy that sets it apart from other competing products in the marketplace.

As we mentioned in our last earnings call, our PIKA rabies vaccine is currently entering Phase III clinical development, and we are taking proactive steps to maximize its commercialization potential once clinical trials are complete. We have established a subsidiary in the Philippines to aid in the advancement of clinical and regulatory processes related to the vaccine's development. This subsidiary will also help us enhance the PIKA rabies vaccine’s commercialization going forward.

In addition, we previously entered into an agreement with a healthcare-focused investment firm to bolster our commercialization efforts of our rabies vaccine franchise, particularly in less-developed countries. Now, as we move closer to bringing our PIKA rabies vaccine to market, we are exploring the potential of establishing strategic partnerships in regards to the commercialization of our PIKA rabies vaccine.

Finally, we are also making clinical trial progress on our longer-term pipeline candidates. PIKA YS-ON-001, our pipeline product targeting multiple indications of solid tumors, continues to progress through its Phase I trial in China. We expect this trial will be completed by the end of the calendar year of 2023, and we hope that we could move this program into Phase II studies in 2024. Meanwhile, our new generation of Hepatitis B vaccine is also making its way through the development process. Unlike most prophylactic Hepatitis vaccines, which are preventative, this product is designed to be a new therapeutic approach against the chronic Hepatitis B infection. We expect the vaccine to enter Phase I clinical trial in calendar year 2024.

To summarize, the first quarter of our fiscal year 2024 saw our top line impacted by the fallout from COVID-related issues we encountered late in 2022. Despite this, the core of our business remains robust, and we have taken the opportunity to reinforce our company's strengths and address our weaknesses. As we advance commercialization of our promising PIKA rabies vaccine and progress towards an exciting new chapter in our company's history, we will remain diligent in our operations and pursue new ways of innovating and growing our business.

I will now turn the call over to our CFO, Ms. Brenda Wu, to discuss our financial results in more detail. Brenda, please go ahead.

Brenda Wu: Okay, thank you, David. I will now provide a closer look into our financials. Please note that all numbers are in RMB terms, that the reporting period is first quarter of fiscal year 2024, ended June 30, 2023, versus the comparable period in fiscal year 2023 ended June 30, 2022, and all comparisons are on a year-over-year basis, unless otherwise stated.

For the first quarter of fiscal year 2024, our revenues were RMB 176.3 million, compared to RMB 205.5 million in the same period of 2023, representing a change of 14.2%. As discussed by David earlier in the call, this was mainly due to COVID-related disruptions affecting raw material supply chains, manufacturing operations and production output at our YSJA rabies vaccine production facilities. These factors negatively impacted batch approvals and doses of finished product available for sale.

Gross profit was RMB 141.6 million, compared to RMB 154.3 million in the previous year, while gross margin improved by five percentage points to 80.3%.

Now, turning to our operating expenses.

Selling and marketing expenses were RMB 79.2 million, compared to RMB 70.5 million in the same period of 2023. The change was primarily driven by our ongoing long-term strategies to enhance promotional and marketing services in order to expand their scope and distribution to CDC and hospital customers, which include city, county, and district-level customers. This targeted expansion aligns with our commitment to increasing accessibility and driving growth in key markets.

General and administrative expenses were RMB 31.8 million, compared to RMB 25.5 million in the same period of 2023. This was mainly due to the increase in professional service fees associated with our status as a publicly-listed entity.

Research and development expenses were RMB 100.6 million, compared to RMB 70.3 million in the same period of 2023. The change was primarily driven by an increase in preclinical and clinical development costs associated with our rabies vaccine pipeline. This increase reflects our targeted allocation of resources in advancing our promising rabies vaccine candidates through various stages of development in line with our commitment to innovation and addressing unmet medical needs.

Net loss was RMB 69.5 million, compared with RMB 19.6 million in the same period of 2023.

Turning to our balance sheet. We had RMB 311.8 million in cash and cash equivalents as of June 30, 2023, compared with RMB 370.4 million as of March 31, 2023.

Finally, I would like to provide some commentary on our financial outlook. Sales of our YSJA rabies vaccine have grown robustly over the last three years and the product continues to experience strong demand from the market. Since we launched the product for sale in late 2020, the market intake of our YSJA rabies vaccine has been consistent and strong.

In part due to this persistent demand, our inventory level of the finished product available for sale has remained low. Given that the YSJA rabies vaccine is the only marketed product contributing to our top-line, and that sales could be affected by multiple factors, we may encounter quarter-to-quarter volatility in terms of revenue numbers or revenue growth. Currently, we are still at the stage of building up our inventory of finished product, and as we are still in the first half of our fiscal year 2024, we are not in a position to provide specific revenue

guidance for fiscal year 2024 at this time. This guidance reflects our current and preliminary views on the market and operational conditions, which are subject to change.

As we navigate through the lingering obstacles posed by late-2022's COVID disruptions, we remain steadfast in our efforts to satisfy the considerable and growing demand for our products in our targeted market territories. As we strategically advance the development of our robust pipeline of product candidates, we will continue to strengthen our business and take advantage of opportunities for growth. Overall, we believe we are well poised to achieve long-term success and create sustainable value for our shareholders.

That concludes our prepared remarks for today. Operator, we are now ready to take questions.

Questions & Answers

Operator: [Operator Instructions]

Our first question today will come from Rachel Yu of Oceanpine Capital.

Rachel Yu: I just have a question for -- I have a question about the revenue in the last quarter. So, I heard you -- if I remember right, you mentioned several factors impact the top line. First is about inventory disruption due to the COVID situation in China in the beginning of this calendar year 2023, and secondly is about the broad relief about the -- of the production facility in the Liaoning Province. So, in your view, which factors impact the top line most, like a different -- most negative result -- impact?

And then the second question is still regarding the revenue. Since the COVID situation is long gone, I think it is -- in the beginning of this year, after that is pretty much already gone, do you expect to still have a lot of lingering effect on the second quarter of the revenue? And then about the lot release by the inspection body -- by the government, when do you expect to -- we can pass that inspection? Yes, that's all my questions. Thank you.

Dr. David Shao: Okay. Rachel, thank you for your questions. These are very excellent questions. Indeed, the main impact coming from the disruptions about the COVID pandemic, as we mentioned already, this involved supply chain disruption on the raw material front, as well as the regular manufacturing operations. So that's really the main cause of the delay of the production and the output of the production.

In terms of lot release time frame, as I mentioned that, I talked about three to four months. That's really a standard of three to four lead time for the lot release, so that's really secondary. The main impact really is coming from the company production step.

And given the timeline, we are just in the mid of the summer. We are experiencing this kind of impact at this moment because, as you know then, the production lead time is five to six months; then in addition of that, we have three to four months' lead time for the lot release. So right now, we are in the middle of this type of delay.

With that being said, we are not really totally in no inventory, no lot release activity at all. We are waiting for additional lot release approval, on an ongoing basis. Why we are talking about this disruption at this moment, just the expectation of our inventory level for the finished product is lower than our original expectation. That's sort of the -- that's the situation we are facing at this moment. We expect this situation will continue to last probably toward the end of the year. That's pretty much I can provide the -- some understanding of the impact on this part.

Operator: Our next question today will come from Greg Aurand of Noble Capital Markets.

Gregory Aurand: I have a couple of questions. The 80% gross margin level is pretty darn good; can you talk about that? Was that related to pricing? Because given the disruptions, the supply chain issues, expanding the margins to 80%, over 80%, is pretty good. So, can you talk about how that got to that level?

Dr. David Shao: Yes, Greg, thank you for this question. Actually, as company manufacturing operations, we have been achieving this profit margin quite consistently around 76% to 80%. So that's what we have been achieving over the past few years. So, it's really meeting our expectations on a regular basis. I'm not sure if I answered your question, or you have additional follow-up on this part?

Gregory Aurand: Yes. That's great, thank you. So, given the disruptions, it's still unusual to see an expanding margin to some extent. I guess I'm looking at, in terms of normal times, where would the margin be going?

Dr. David Shao: Okay. Actually, historically, if you look back at our gross margin, it has been between, like, a 76% or 79% or 80%. We have been operating in this range, actually.

Gregory Aurand: Mm-hm.

Dr. David Shao: Yes.

Gregory Aurand: Okay. Thank you.

Dr. David Shao: Um --

Gregory Aurand: Was there any pricing impact? I'm sorry. Was there any pricing impact, do you know?

Dr. David Shao: Yes, yes. That's another aspect I just want to mention. We did experience a slight price increase over the last three years' time frame, so indeed, the unit price -- or the selling price increased at a single-digit annual rate. On the other hand, we are able to keep the production efficiency and the profitability, along with the price increase.

Gregory Aurand: Excellent. Thank you. If you don't, mind, I'd like to ask another question, or I could get in the queue if you want to go to somebody else, but my question is related to your

competition. It's quite a competitive market. Are they experiencing similar issues to supply chain and production that you are?

Dr. David Shao: Actually -- yes, Greg, actually, indeed, it not only impacts the vaccine production business. It also impacts the other pharmaceutical industry in China as well during the pandemic period. Just to give you an example, some of the starting materials are imported, not really produced in China. As you could imagine that, during those periods, it's very difficult for the shipment of delivery of raw material from overseas to China and across continents. So, a lot of companies experienced this type of situation. And also during those periods, you know, vaccine products sometimes use very common starting material or media. And during those periods, they were the priority, supply was prioritized for COVID-related vaccine production, because during those periods, people wanted to make sure the starting material would be sufficient enough for COVID vaccine production. For other vaccine production, these became secondary.

So, there's some of the logistic issues during those periods and also during the supply chain disruption situation.

Operator: Our next question will come from Hunter Diamond of Diamond Equity Research.

Hunter Diamond: Some of my questions were answered, but I have one more question. Can you discuss some of the supply-chain-related manufacturing productivity initiatives you're taking, specifically related to YSJA and the PIKA vaccine, so what you're doing to boost the manufacturing capacities going forward and the productivity?

Dr. David Shao: Okay. Hunter, thank you. That’s an excellent question. I'll just give you an example. For example, in our production process, there's one particular starting material initially we have to rely on imported resources, and right now, given the situation we've experienced, we try to make sure, for the same starting material, we can secure multiple suppliers. So that's what we are doing at this moment. And also we try to set up long-term contracts with a potential supplier, to make sure during the production cycle we would have sufficient starting material to work with.

But this is an ongoing process. What we learned from the pandemic period will help us to avoid such disruption in the future. But you know, when we're talking about pharmaceutical and the biotechnology products, we probably just focus on recent developments and some clinical data. Actually, behind that, the production is a very complicated, very important process that involves multiple starting materials and very long-term production cycle. So, if each of these steps have a problem, that causes a delay or negative impact for the project. So that's why we emphasize a lot making sure we could have multiple suppliers for each individual ingredient of starting material, just to give you an example.

Hunter Diamond: Great. No, I appreciate that. That makes perfect sense in a way to combat future disruptions, so again, that's all I have. It was a fairly comprehensive call, and some of my questions were answered. But thank you for taking that one question.

Dr. David Shao: Thank you, Hunter.

Operator: Our next question today is from Sid Rajeev of Fundamental Research.

Sid Rajeev: You mentioned that you're expecting supply chain issues to be persistent in the coming quarters. How should we look at Q2, Q3 revenue? Can we expect a similar 14% decline?

Dr. David Shao: Thank you, Sid. Actually, we are not at a position to give guidance for -- like for the next quarter, financial performance. But as we indicated, that's because there is indeed a lingering effect on the finished product, the inventory level. As I mentioned, we do have inventory for delivering to the customer at this moment, but actually, we would like to have more inventory through an ongoing approval process to accumulate our inventory. Hopefully after a couple of quarters from now, we can have sufficient inventory to meet the demand from our customer orders. That's pretty much we can share with you at this moment.

Sid Rajeev: Understood. In your prepared remarks, you talked about procuring raw materials from outside sources internationally. Is that something that you can pursue to mitigate supply chain issues going forward? Where will you procure from? It seems like you can diversify your imports significantly by doing so.

Dr. David Shao: Absolutely. And I'll try to be specific on this particular question. When we try to procure additional supply or additional supplies -- starting material, we need to conduct a comprehensive equivalent test, to make sure this potential new supply starting material would be equivalent and can be completely replaceable with our existing starting material. So, this process has very stringent requirements, and they would need to be submitted and approved by the regulatory authorities in China. So, it's quite a long process, but we are working on that end.

Sid Rajeev: Okay. Just one more question. The North American market investors are not really familiar with other Chinese vaccine companies or directly comparable companies. Are you able to provide a few names so that we can start following them, and kind of make comparisons, and see -- and kind of have a benchmark of the performance of other companies there?

Dr. David Shao: Yes, that's good. Actually, Sid, I think we can come back with you after the call. We can provide additional background information to better help you to understand the vaccine players and the industry landscape in general. We do have some information we could share with investors and analysts, no problem.

Operator: [Operator Instructions]

Our next question today will come from Howard Halpern of Taglich Brothers.

Howard Halpern: I just have one question. Everything was pretty much gone over. But based on the disruptions that you talked about, is there any impact on the next-generation trial that you plan on starting soon?

Dr. David Shao: Howard, thank you very much. That's a really very important question as well. Just for your information, the production bioengineering process is similar to YSJA rabies vaccine, but our new-generation PIKA rabies vaccine production engineering protocols are kind of different. That's why we didn't feel the impact from that. And also, since the PIKA rabies vaccine is at the Phase III clinical stage, and we have finished the production of the clinical samples for this multi-country, multi-center trial, as we mentioned that, we're going to do that trial in the coming months with 4,500 subject enrollment and hopefully can complete the enrollment in a timely manner. So, all the clinical samples have been produced and either shipped to the clinical site or ready to ship to the clinical site, so we have no issues related to our PIKA rabies vaccine Phase III trial.

Operator: [Operator Instructions]

At this time, we will conclude our question-and-answer session. I would like to turn the conference back over to management for any closing remarks.

Alyssa Li: Thank you again for joining our call today. If you have any further questions, please feel free to contact us or submit a request through our IR website. We look forward to speaking with everyone during our next call. Have a good day.

Operator: The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.