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SIGA Technologies

Fourth Quarter and Full Year 2024 Earnings Call

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CORPORATE PARTICIPANTS

Dr. Diem Nguyen, *Chief Executive Officer*

Dan Luckshire, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Jyoti Prakash, *Edison Group*

Brian Adams, *Carter Terry*

PRESENTATION

Operator

Welcome to the SIGA Business Update Call.

Before we turn the call over to SIGA Management, please note that any forward-looking statements made during this call are based on management's current expectations and observations, and are subject to risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. SIGA does not undertake any obligation to update publicly any forward-looking statements to reflect events or change of circumstances after this call.

For a discussion of factors that could cause actual results to differ, please see the Company's filings with the Securities and Exchange Commission, including, without limitation, the Company's Annual Report on Form 10-K for the year ended December 31, 2024, and its subsequent reports on Form 10-Q and Form 8-K.

With that, I will now turn the call over to Diem Nguyen, Chief Executive Officer of SIGA. Diem, please go ahead.

Dr. Diem Nguyen

Good afternoon, everyone, and thank you for joining today's call and review of our business results for the fourth quarter and full-year of 2024. I am joined by Dan Luckshire, our Chief Financial Officer, and we appreciate this opportunity to provide an update on our company. After the update, we'll be happy to answer your questions.

I'm pleased to share that 2024 was a year of impactful execution and strong financial performance for SIGA. In 2024, we also made considerable progress on several initiatives to drive shareholder value including: one, continuing our partnership with the U.S. government; two, advancing regulatory approvals for TPOXX; and three, cultivating strategic partnerships to expand global access to TPOXX.

With product sales of $133 million, up approximately 2% from 2023, we delivered the second consecutive year of product sales growth, reinforcing the critical role that TPOXX and a comprehensive smallpox preparedness program play in strengthening national security. Additionally, our results highlight the strength of our financial position.

Of the $133 million in product sales, about $80 million was generated in the fourth quarter from a diverse mix of revenue sources, led by deliveries of oral and IV TPOXX to this U.S. Strategic National Stockpile. This was followed by deliveries of both oral and IV TPOXX to the U.S. Department of Defense and deliveries of oral TPOXX to international markets. The latter included a notable sale in East Asia for $11 million of oral TPOXX, which is more than double the size of the largest prior individual TPOXX sale in the region. This latest international milestone follows the first sale of TPOXX in Africa in the third quarter in response to a request from the Ministry of Health in Morocco.

Beyond the 2024 top-line financial results, we have taken important steps to advance our key initiatives and strengthen our Company, which we believe will produce shareholder value over time. I would like to highlight some of these steps.

We continue to make progress in our international markets. Two examples stand out. First, midway through 2024, our Company assumed responsibility for promoting TPOXX outside the U.S. from Meridian Medical Technologies. This action has brought us much closer to our current and potential future customers, thereby enabling us to better understand and meet their needs. We've started to build an international sales and marketing infrastructure in 2024, and plan to continue to invest in that infrastructure to achieve our full potential in the international markets. We believe our conversations and actions will yield positive results over time.

Second, as announced earlier this year, we achieved another international regulatory approval when Japan's Pharmaceuticals and Medical Devices Agency, in collaboration with the Japan Ministry of Health, Labour, and Welfare, approved TEPOXX for the treatment of a broad range of orthopoxviruses. This approval marked another important milestone in our efforts to expand access to TPOXX.

Additionally, it coupled with the growing sales of TEPOXX in East Asia, reinforces the value of antiviral stockpiling to ensure supply resilience during immediate crisis response to safeguard communities and individuals against smallpox. To obtain this approval, and in collaboration with our local partner, Japan Biotechno Pharma, we submitted a robust data package, which included studies involving healthy human volunteers, non-human primates, and rabbits. No other drug approved to treat smallpox or any other orthopoxvirus is supported by such a comprehensive and extensive data package.

Shifting gears, on cultivating strategic partnerships, in October, we announced an exclusive license to a portfolio of preclinical, fully human monoclonal antibodies from Vanderbilt University that have the potential to treat a broad range of orthopoxviruses, including smallpox and mpox. Leveraging our existing capabilities to create new opportunities over the long term, we believe this portfolio has the potential to complement our TPOXX franchise and provide patients with additional therapies in this space.

While monoclonal antibodies represent an early-stage component of our pipeline, our TPOXX post exposure prophylaxis program for smallpox, or PEP, is far more advanced. We continue to collaborate with the CDC, in consultation with the FDA, to complete the analysis of the samples collected to support the study's immunogenicity objective. As a reminder, the safety objective has already been successfully achieved. The CDC's work is underway, and we believe they will complete their analysis around the middle of this year. Based upon their projected timeline, we are now targeting an FDA submission for the PEP indication in early 2026.

In addition to our successes, we've also faced some challenges this year given the PALM007 and STOMP clinical trial results in mpox. While the results of these trials were not a surprise given the mechanism of action of TPOXX and the design of the trials, they have led to some important discussions about TPOXX that I'd like to address today.

By the way of background, TPOXX was developed as a treatment for smallpox with the primary goal of reducing mortality and saving lives in the event of an outbreak. Approval under the FDA's rigorous Animal Rule, TPOXX is supported by extensive studies demonstrating its safety and efficacy in reducing mortality

from smallpox. Since smallpox vaccination programs were discontinued several decades ago, herd immunity has diminished, leaving populations vulnerable to its potential reintroduction.

For example, in the U.S., approximately 190 million people were born after the end of routine vaccination, leaving these Americans vulnerable. Additionally, the robustness of the immune response in those vaccinated more than 50 years ago cannot be determined. As such, the potential for its intentional reintroduction remains a serious concern.

For PALM007 and STOMP, SIGA donated the product to trial sponsors to help advance mpox research and support the response to the 2022 global mpox outbreak. Because mpox is a far milder and largely self-resolving disease with a much lower mortality rate than smallpox, these trials were designed to measure the time for all lesions to heal between patients receiving TPOXX and those receiving placebo. While these studies did not show statistical significance difference between tecovirimat and placebo on this primary endpoint, the PALM007 results did signal potential benefits for patients treated early or with severe disease.

Generally speaking, viruses replicate faster in the initial stages of infection, and administrating antivirals early helps curb virus replication before reaching its peak load, thereby reducing the severity of the disease. This principle was exemplified during the COVID-19 pandemic, where timely administration of antivirals proved critical in improving patient outcomes. The same principle applies to TPOXX.

Tecovirimat works to reduce viral release from infected cells. Based upon tecovirimat's mechanism of action, we believe treatment would be optimized when administered early in symptoms or ideally post-exposure prophylaxis. The early phase of disease includes viral amplification and dissemination throughout the body. As the disease progresses, the immune system works to clear the virus already released from the cell after replication.

In PALM007, we saw the potential benefits for patients treated early or with severe disease. We're currently assessing viral load impact in mpox patients over time as we expect reduction in virus load with tecovirimat administration early, consistent with our non-human primate models. Both PALM007 and STOMP enrolled patients at later stages of disease, a median of about 5.9 days and 8 days, respectively, after self-reported symptom onset. We believe these trials are not necessarily reflective of how or when the drug should be used based on its mechanism of action and potential value in a smallpox outbreak. We believe TPOXX remains a vital countermeasure for reducing mortality from smallpox.

In a comprehensive preparedness plan, antivirals provide a critical line of defense. Complementing vaccines, antivirals can be used to treat an infection in patients who have not been vaccinated or who did not benefit from vaccination. Certain antivirals have the potential to prevent onset of a viral illness after exposure to the virus. The relationship between vaccines and antivirals is particularly important as we face the growing challenge of emerging infectious diseases and threats of bioterrorism. Strategic stockpiling of antivirals helps ensure a swift, coordinated response when disaster strikes.

Looking forward, we believe securing a new contract for the continuing supply of TPOXX to the Strategic National Stockpile, or SNS, represents an opportunity to enhance our Company's long-term potential and help advance our national security through bioterrorism preparedness. Since the new U.S. Administration took office, we have seen many bold initiatives launched and Executive Orders enacted, with more changes expected as new leaders are nominated, confirmed and put in place. With any change of Administration, this takes time. While change can create uncertainty, it can also create long-term opportunities as priorities are clarified and new policies are enacted to enhance national security. We will continue to monitor these developments and assess the potential impact, if any, on our Company.

Whatever transpires, we believe we are well positioned to engage with the new ASPR as well as other senior officials on the nature and timing of an RFP for a new contract for TPOXX. As a reminder, ASPR is within the U.S. Department of Health and Human Services, or HHS, and houses the Center for the Biomedical Advanced Research and Development Authority, or BARDA, and SNS. For reference, SIGA

has been providing TPOXX to the ASPR for more than a decade, and national security is an issue that transcends political considerations.

We believe the new Administration is committed to maintaining a robust preparedness strategy, which includes the supply of antiviral therapies to treat smallpox. Furthermore, our current 19C contract was awarded under President Trump's leadership in 2018. With this in mind, we stand ready to negotiate with the new ASPR with the objective of completing a new contract in 2025.

In summary, this is a dynamic time for SIGA. We are strong, resilient and profitable. Our strategy is yielding results. Our disciplined approach to capital management gives us optionality. Our TPOXX franchise meets a critical need for smallpox preparedness, and our team has the expertise to drive results over the long term in the best interest of our customers and shareholders. In short, with a strong foundation, we believe we are well positioned for the future and the opportunities ahead.

With that, I'll turn it over to Dan to review the financial results in more detail.

Dan Luckshire

Thanks, Diem. As noted earlier in the call, SIGA's product sales for this year surpassed prior year sales. This represents the second straight year of sales growth and a new high watermark for annual sales since FDA approval of TPOXX in 2018. Product revenue for full-year 2024 was $133 million. Of this amount, $80 million was recognized in the three months ended December 31, 2024.

In the fourth quarter, $51 million of oral TPOXX and $9 million of IV TPOXX was delivered to the Strategic National Stockpile, or SNS;$9 million in mostly oral TPOXX, and a small amount of IV TPOXX, was delivered to the U.S. Department of Defense; and there was an $11 million sale to an international customer in the East Asia region. To reiterate a comment made earlier in the call, the international sale in the fourth quarter represents a milestone in that it is more than double the size of the largest prior individual TPOXX sale in the East Asia region.

With respect to product sales for the full-year 2024, the $133 million amount comes from a diverse mix, similar to the diversity in the fourth quarter. The revenue mix includes: $74 million of oral TPOXX sales to the SNS; $26 million of IV TPOXX sales to the SNS; $10 million of oral and IV TPOXX sales to the U.S. Department of Defense; and, $23 million of oral TPOXX sales to 13 international customers.

In addition to product-related revenues, the Company also had research and development revenues. For the three months and 12 months ended December 31, 2024, research and development revenues were $1.6 million and $5.4 million, respectively.

Pre-tax operating income, which excludes interest income and taxes, was approximately $57 million for the three months ended December 31, 2024. For the full year 2024, pre-tax operating income was approximately $70 million. In comparison, there was pre-tax operating income for the three months and 12 months ended December 31, 2023, of approximately $92 million and $84 million, respectively. I would like to note that differences between pre-tax operating income margin in 2024 and 2023 reflect different product mixes in those periods.

Net income for the three months ended December 31, 2024 was approximately $46 million. For the 12 months ended December 31, 2024, net income was approximately $59 million. In turn, fully-diluted income per share for the three months ended December 31, 2024, was $0.63. For the full year 2024, fully-diluted income per share was $0.82.

Throughout 2024, the Company continued to maintain a strong balance sheet through an abiding commitment to financial discipline. At December 31, 2024, the Company had a cash balance of $155 million and no debt.

Looking forward to 2025, I would like to note that we had a $70 million outstanding order balance at December 31, 2024, which we expect to deliver in 2025.

This concludes the financial update. At this point, I will turn the call back to Diem.

Dr. Diem Nguyen

Thank you, Dan. With that, we would like to open the call for questions.

Operator

Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. If you have a question, please press star, followed by the number one on your touchtone phone. You will hear a prompt that your hand has been raised. Should you wish to decline from the polling process, please press star, followed by the number two. If you are using a speaker phone, please lift the handset before pressing any keys. One moment, please, for your first question.

Your first question comes from the line of Jyoti Prakash from Edison Group. Your line is now open.

Jyoti Prakash

Hi, thank you for taking my questions. My first question relates to oral TPOXX deliveries. We understand that around $60 million has been delivered from the most recently exercised BARDA option. Have there been any additional deliveries in 2025 to date? Can we expect the entire remaining order to be delivered in the first half given the expected RFP timelines with the U.S. authorities?

Dr. Diem Nguyen

Thanks, Jyoti. I'll let Dan answer that question.

Dan Luckshire

Yes. Thanks for the question, Jyoti. As noted in our prepared remarks, we had $70 million of outstanding orders at December 31, 2024. Most of these orders—or these orders mostly consist of remaining deliveries of oral and IV TPOXX to the SNS under existing orders. We currently expect those deliveries to start in the second quarter based on coordination with the United States government. We expect all $70 million of the outstanding orders to be delivered in 2025.

There's one, at the very end, you mentioned the RFP. Just to make sure for clarity purposes, just to highlight that the RFP process is a separate process from the delivery process under the 19C contract. In fact, the RFP timing is not impacted by the delivery timing. I just wanted to make that clear.

Jyoti Prakash

Thanks a lot. That's really helpful. My second question relates to your cash position. You ended the year with a strong cash balance of $155 million. Can we expect you to announce another special dividend this year as you've been doing every year since 2022?

Dan Luckshire

I'll also take that question, too. Before I get into the direct answer, let me just give you some background. As a starting point, our capital management strategy is meant to be dynamic and tailored to optimize positive outcomes for our shareholders both in the short term—balancing the short-term and the long-term. This approach has been used over the past series of years.

With that, the timing of a special cash dividend each year is influenced by several factors, which we regularly review. Some of the factors include cash flow performance, capital allocation priorities, external market conditions. There's a series of factors that we're continually reviewing.

When you look at prior years, there's really no specific timeline for when special cash dividends occur. In '22 and '23, the Board of Directors declared a special cash dividend in May, which were paid in June. Then in '24, the special cash dividend was declared in March, and it was paid in April. There's some movement in terms of timing.

When you sort of bring all these things together, to your question, and when you take all these things into account, we currently anticipate making a capital management decision in the second quarter, which is consistent with the timing for most prior years.

Jyoti Prakash

Great. My next question relates to your international growth. First of all, congratulations on receiving the regulatory approval in Japan for TEPOXX. Can you provide some more details in terms of your distribution agreement with Japan Biotechno Pharma?

Just to follow-up on that, you made $11 million of international sales in the last quarter. Does that relate to delivery to Japan's Strategic National Stockpile?

Dan Luckshire

On the first part of the question, the terms of the distribution agreement with Japan Biotechno Pharma, or JBP, those terms have not been disclosed. What we can say though is that the distribution agreement with JBP or within other countries were different in nature than the promotion agreement we had with Meridian. The key point here is that distribution agreements will not have the same level of fees that were paid to Meridian. It's a much more efficient model and financially better for us.

On the second part of that question, in terms of the $11 million international sale, right now, at this time, we're not currently disclosing that customer. As mentioned in the prepared remarks, the customer is located in the East Asia area, but we're not disclosing the specific customer.

Jyoti Prakash

Thank you for that. I have another couple of questions. The next one is related to the mpox opportunity. How do you see that evolving given the results from the PALM007 and STOMP trials? We understand that there were subsets of patients who saw good results in the PALM007 trial. Is there any plan to adjust the design of the remaining trials to focus on these particular subset of patients?

Dr. Diem Nguyen

Jyoti, thanks for that question. I'll take this one. Just an overarching concept, we are continuing to work with NIAID. They are specifically the PALM007 and STOMP trial sponsors. We are working with them to fully analyze the clinical data, including reviewing data from certain subgroups, as you mentioned, to determine what types of patients may potentially benefit the most from tecovirimat as well as the optimal treatment regimen. Once this data analysis is complete, we will then be in a better position to determine the best path forward from both a clinical trial and regulatory perspective.

I think it is important to note that while we learned a lot from these trials, they certainly had some limitations associated with the trial design. The primary objective was to provide access from a humanitarian perspective. That was particularly consistent in the PALM007. These trials are not designed by SIGA, and they were not designed with drug development in mind. As a result, we expressed some of the limitations associated with the mechanism of action. Antivirals generally work based on how their

mechanism of action is executed. Tecovirimat's specific mechanism of action, the typical patient profile, the design of the trials, it's not unexpected these trials did not meet their primary endpoint to full resolution of all lesions.

As with the case of STOMP and PALM007, SIGA is not the sponsor of these ongoing trials, so we do not have the ability to modify the designs based on learnings with current ongoing trials. Having said that, Jyoti, we will continue to evaluate the potential benefit of tecovirimat treatment on mpox patients and will then design and execute on further studies accordingly.

Jyoti Prakash

Great. That's super helpful. I have one final question. What do you think of the recent funding cuts for the NIH by the Trump administration? Do you see any sort of flow-through impact on your expected RFP for TPOXX?

Dr. Diem Nguyen

Thanks, Jyoti. We can only speak on behalf of SIGA. First and foremost, I would say that SIGA has a long history of collaboration with the U.S. government agencies, including through four administrations, that is inclusive of Biden, Trump, Obama and Bush. These relationships naturally evolve following changes in leadership from an administration perspective.

For now, our focus remains on maintaining strong partnerships and continue to play an important role in supporting the U.S. national security and public health initiatives. Based on our experiences and conversations today, we do believe national security is of utmost importance, and it does transcend partisan politics and that the new administration is committed to maintaining a robust preparedness strategy, which does include supply of antiviral therapies to treat smallpox. Whatever transpires during this transition period, we believe we are well positioned to engage with the new ASPR as well as other senior officials on the nature and timing of the RFP for a new contract for TPOXX. At this time, any further comment would be purely speculative in nature.

Jyoti Prakash

Okay. Thank you so much. No further questions, and congratulations again on the strong quarter.

Dr. Diem Nguyen

Thanks, Jyoti.

Operator

As a reminder, if you have a question, please press star, one on your telephone keypad.

Your next question comes from the line of Brian Adams from Carter Terry. Your line is now open.

Brian Adams

Thank you very much and great year. A couple of quick questions. On the, kind of, the process of re-engaging with BARDA and potentially, again, blue skies, gray skies looking forward, if this were a baseball game and it's nine innings and we're reupping the contract for, we all hope it to be, maybe a number that would be greater than the $555 million or $575 million of the original contract six years ago, where do you think we stand on this? Are we in the fourth inning, fifth inning? You had kind of alluded to, ma'am, Dr. Nguyen, that would—some kind of decision would be made this year. Would there be a COLA increase, maybe a number in the $700 million to $800 million range? That's my first question.

Then secondly, the inventory that's on the book shows $49 million. What exactly is that? Is that the value of the drug that can be deployed? I'm assuming that will meet a portion of the $70 million of the legacy contract that still needs to be filled. Those are my first two questions.

Dr. Diem Nguyen

Hi, Brian, thanks for the thoughtful questions. I will target the first question and then let Dan talk you through with the inventory. First and foremost, I would start by saying that we have continued conversations with BARDA and SNS in terms of tecovirimat and it as the primary treatment of choice for smallpox. There is a continued re-enforcement of its importance to the U.S. government from a preparedness perspective. We have talked quite a bit about manufacturing strategies as well as potential volume.

However, Brian, we have not identified a specific range of volume to date. I can only say based on the macro dynamics that we're facing in our environment today, that the smallpox threat continues to increase. Now whether that be from geopolitical tensions or from naturally occurring concerns based on a vulnerable patient population that may not be vaccinated, we think that this is certainly an important time to reflect on the volume requirements. That discussion still remains to be executed or discussed. Dan?

Dan Luckshire

Yes. On the question about inventory, and it ties a little bit into what Diem was saying in that, given what's happening on the geopolitical front, which is—it keeps getting ratcheted up, but this has been something that's been building for a series of years in terms of risk. With that, we've been trying to be proactive in terms of having product throughout the supply chain. Within that inventory balance, it does include product to be delivered on that $70 million of outstanding orders.

But also, it includes a fair amount of API, so that when there are future orders, we have the ability to be responsive in a very efficient way and in a scaled manner. We are trying to be proactive, but that amount does also include cost of product to be delivered under the existing orders.

Brian Adams

Okay. Then just asking a very pointed question and not to make anybody difficult, but I want to ask this because it was a really significant company-specific situation. What is the continued, if any, fallout from Dr. Varma in regards to questions from your peers or from NIH or BARDA in regards to efficacy of basically TPOXX to treat the early stages of mpox? You are and have rightfully refuted it. But has it impacted sales, I guess, from what you're hearing or seeing?

Dr. Diem Nguyen

Brian, thank you asking. I want to start by saying that we have had over a decade of a relationship with BARDA as well as SNS from a U.S. perspective. This started originally from the co-development of our product tecovirimat, where we have been incredibly transparent and collaborative in terms of our science. This has then progressed to the procurement of the stockpile of tecovirimat.

Jay had been at SIGA for less than a year. In terms of his contributions, I would say that it's minimal, if not none. He was not part of the development of tecovirimat, and he certainly was not part of the clinical trial execution. We stand by our science. We stand by the data, and so do our partners in terms of the importance of an antiviral like tecovirimat as well as the preclinical and clinical data that shows its safety, and finally, the preclinical data that demonstrates efficacy.

Brian Adams

Okay, great. Then my final question, and I applaud you for making the deal, I guess, with Vanderbilt a few months back. But with the cash war chest that you've got, it would be my recommendation as a shareholder and a portfolio manager that you—and you're probably already looking at this, but to build out yourselves beyond arguably one or two-trick pony, so to speak, or stable. Are there other, either drugs or bioterrorism prophylaxis portfolios or drugs that you're looking at right now that you could tuck in to your portfolio that would be another source of potential revenue and/or income for you down the line?

Dr. Diem Nguyen

Brian, I would actually say that coming into SIGA almost a year ago, one of the priorities I have is to maximize the TPOXX franchise, which includes global expansion from a registration perspective. But the second aspect is looking at potential diversification of the pipeline. You saw thedegree of activity we had pursued in 2024. I'd like to continue to pursue in 2025 portfolio diversification, exactly to your point.

Brian Adams

Okay. Thank you very much. That's all I had. Appreciate it. Thank you very much.

Dr. Diem Nguyen

Thanks, Brian.

Operator

There are no further questions at this time. I will now turn the call back to Diem. Please continue.

Dr. Diem Nguyen

I wanted to thank everybody for their time today and joining us for today's call and for your ongoing interest in SIGA. We look forward to speaking to you again in our first quarter call. Have a good rest of your evening. Thank you.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for your participation. You may now disconnect.