SIGA Technologies, Inc.
Q3 2024 Earnings Call

Event Date: November 7, 2024

CORPORATE PARTICIPANTS

Diem Nguyen, *Chief Executive Officer*

Daniel Luckshire, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Jyoti Prakash, *Edison Group*

PRESENTATION

Operator

Welcome to the SIGA business update call. Before we turn over the call 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 from the forward-looking statements. SIGA does not undertake any obligation to update publicly any forward-looking statement to reflect events or changed circumstances after this call. For a discussion of factors that could cause 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, 2023 and its subsequent reports on Form 10-Q and Form 8-K.

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

Diem Nguyen

Good afternoon, everyone, and thank you for joining today's call and the review of our business results for the third quarter 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 with $122 million of procurement orders secured in the third quarter, SIGA continues to sustain its strong business momentum. These new orders position us well to extend our strong year-to-date revenue performance, which is outpacing revenues in the comparable period last year.

Additionally, I would like to note that our product sales so far this year include a diverse mix of revenue sources, led by oral and IV TPOXX deliveries to the U.S. Strategic National Stockpile. Internationally, year-to-date sales include deliveries to new customers, one of which represents our first sale of oral TPOXX in Africa in response to a request from the Ministry of Health in Morocco.

At the end of the third quarter, outstanding procurement orders were $146 million. This significant balance of outstanding orders positions us to recognize substantial revenues in the fourth quarter of 2024 and into 2025, demonstrating the continued strong demand for TPOXX. Please note that this outstanding order balance includes most of the $112.5 million order from the U.S. Government under the 19C contract announced in July, which we began shipping toward the end of September and continued into October.

We believe year-to-date sales, as well as the outstanding orders built over the past several months, underscore our company's financial strength and resilience. Our focus continues to be on SIGA's long-term performance, as we have multiple strategic opportunities to drive and expand our revenue base and earnings over time.

Looking forward, we believe securing a new contract for the continuing supply of TPOXX to the Strategic National Stockpile, or SNS, represents a significant opportunity to enhance our company's momentum and long-term earnings potential, as well as do our part to advance our nation's public health preparedness.

We believe our ongoing, productive conversations with a wide range of government officials positions us well as we prepare for the Administration of Strategic Preparedness and Response, known as ASPR, to take the first step in the process which we expect would result in a new contract for TPOXX. As a reminder, ASPR is within the U.S. Department of Human Services, or HHS, and houses the Center for the Biomedical Advanced Research and Development Authority, or BARDA, and the SNS.

We believe our dedicated team is well prepared to support this crucial public health initiative. Based on these conversations, we are confident in the U.S. Government's enduring commitment to maintaining robust public health preparedness and the supply of antiviral therapies to treat smallpox.

Importantly, at SIGA, we believe that effective pandemic preparedness requires both vaccines and antivirals as neither alone can fully address the complexity of an outbreak. While vaccines play an important role by preventing disease and building immunity, they may not be immediately available or effective for everyone. Antivirals, meanwhile, offer a critical line of defense by treating infections in real time, and reducing the severity and spread of illness. Together, these tools provide a comprehensive approach to managing a pandemic, ensuring both preventive measures and timely treatments are available.

We anticipate working towards a new comprehensive long-term agreement spanning five years to 10 years. As a framework reference, our last contract executed in 2018 was valued at $546 million. Given the many changes anticipated to take place over the coming weeks in the federal government, the exact timing of the necessary steps remains to be determined. Please keep in mind that health security is a bipartisan issue with strong alignment across both parties and transcends elections and political considerations. This has been reinforced by our experience with administrations from both parties. In fact, our last two contracts were awarded under different administrations, specifically President Obama and President Trump.

In summary, we're targeting the issuance of a new SNS contract in 2025, which we expect would include an initial order under such contract. Such a contract would further our shared goal of protecting public health through continued partnership with the U.S. Government.

Shifting gears, I'm pleased to share that we recently announced an exclusive license to the portfolio of pre-clinical, fully human monoclonal antibodies from Vanderbilt University that have the potential to treat a broad range of orthopoxviruses, including smallpox and mpox. This portfolio of monoclonals expands our pipeline, complements our TPOXX franchise, and offers the potential to develop additional therapies in this space. Further, it opens the door to new long-term growth opportunities in collaboration with government partners to offset development investments. The U.S. Department of Defense is currently funding the development of these monoclonals through Phase 1 via a third-party contract manufacturing organization with proven expertise in biologics development and manufacturing. Assuming the data are positive on these future studies, we plan to explore collaborations with government stakeholders and with their input, pursue the development of these monoclonals to meet the needs of patients and public health. Our efforts will strive to develop this portfolio over the next several years efficiently, without requiring significant use of the Company's cash resources to progress. The license marks an important step forward in our strategy to leverage our existing capabilities to create new opportunities for growth over the long term.

Regarding the TPOXX post-exposure prophylaxis program for smallpox, or PEP, we continue to collaborate with the CDC, in consultation with the FDA, to complete the analysis of samples collected to support the study's immunogenicity objective. The CDC recently began gearing up to perform the re-analysis and is targeted to complete its work in the first half of 2025. As such, we are planning for an FDA submission of the PEP indication in the third quarter of 2025.

As we announced on August 15, the National Institute of Allergy and Infectious Diseases, or NIAID, shared top-line results from a preliminary analysis of the PALM 007 trial. While the study did not meet its primary endpoint of a statistically significant improvement in time to lesion resolution within 28 days for mpox patients in the Democratic Republic of the Congo who were treated with tecovirimat versus placebo, the results from this trial were not surprising due to the humanitarian considerations of the study design. Nonetheless, we are encouraged by the data showing tecovirimat's potential benefit in two important patient groups, first, those patients treated early, and second, those with severe disease. We believe additional trials are warranted to explore the potential benefits of TPOXX as an mpox treatment in these and possibly other patient populations.

Several additional mpox studies are currently being conducted by trial sponsors around the world and are expected to help inform a deeper understanding of the potential of tecovirimat to benefit mpox patients. Four trials are currently enrolling patients, including STOMP, UNITY, PLATINUM-CAN, and EPOXI. The largest of these is STOMP, sponsored by NIAID, and is enrolling patients primarily in the U.S. and South America. It's progressing well with about 670 patients enrolled as of the first week of October, up from 515 reported in our last call.

I would highlight that TPOXX has demonstrated a strong safety profile and is well tolerated by patients. This is supported by preclinical safety and toxicology studies in numerous animal models, including mpox infected non-human primates, Phase 3 clinical data with healthy volunteers, and clinical observations in mpox disease patients. Additionally, more than 2,000 mpox patients have participated in clinical trials to assess the efficacy of TPOXX for mpox treatment, and more than 8,000 patients have been administered TPOXX for compassionate use as the preferred antiviral to treat mpox disease. Furthermore, TPOXX has demonstrated effectiveness as an antiviral and PEP treatment for survival and reduction of body lesions and viral load in non-human primates infected with lethal amounts of mpox virus. Additionally, TPOXX has been shown to improve survival and reduced lesions in non-human primates infected with smallpox. Based on the totality of the scientific evidence, we believe this diverse and expansive collection of data sources highlights why TPOXX has received regulatory approval for smallpox in the U.S. and Canada and regulatory approval in the EU and the U.K. for a broad orthopoxvirus label, including smallpox and mpox.

In Japan, we are actively engaged in discussions with our partner, Japan Biotechno Pharma, and regulators regarding the pending new drug application for TPOXX to treat smallpox, mpox, cowpox, and complications due to the vaccinia virus. Based on the standard review timeline, we expect a final regulatory decision by early next year.

In summary, this is an exciting and dynamic time for SIGA. We are strong, resilient, and profitable. Our strategy and prudent capital management is delivering solid results, and we believe make us well positioned for the future. Additionally, our TPOXX franchise meets a critical need for smallpox preparedness, and our team has the expertise to drive long-term results which we believe will produce sustainable growth and shareholder value over time.

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 the nine months end of September 30, 2024 continue to outpace product sales for the comparable period in 2023. Product revenue for the nine months ended September 30, 2024, was $53 million. Of this amount, $9 million is related to the third quarter. In the third quarter, there was an $8 million oral TPOXX delivery to the U.S. Strategic National Stockpile or SNS, and $1 million of international sales. The $8 million oral TPOXX delivery represents the first delivery to the SNS in connection with the $112.5 million order under the 19C contract, which was announced in July. The international sales amount includes the first sale to Africa.

With respect to product revenues for the nine months ended September 30, 2024, the $53 million amount comes from a diverse mix, including: $23 million of oral TPOXX sales and $17 million of IV TPOXX sales to the U.S. Government under the 19C contract; $12 million of international oral TPOXX sales to 12 countries; and $1 million of oral TPOXX sales to the U.S. Department of Defense.

In addition to product-related revenues, the Company also has had research and development revenues. For the three and nine months ended September 30, 2024, research and development revenues were $1 million and $4 million, respectively.

Pre-tax operating income, which excludes interest income and taxes, was $0.5 million for the three months ended September 30, 2024. For the nine months ended September 30, pre-tax operating income was $13 million. In comparison, there was a pre-tax operating loss for the three months and nine months ended September 30, 2023 of $1 million and $8 million, respectively.

Net income for the three months ended September 30, 2024 was $1 million. For the nine months ended September 30, net income was $13 million. In turn, fully-diluted income per share for the three months ended September 30, 2024 was $0.02, and for the nine months ended September 30, fully-diluted income per share was $0.19.

At September 30, 2024, the Company continued to maintain its strong balance sheet, with a cash balance of $99 million and no debt. I would like to note that the Company has maintained its strong balance sheet while also returning substantial cash to shareholders. As a quick reminder, on April 11, SIGA paid a cash dividend of $0.60 per share, which amounted to a $43 million payment to shareholders.

Looking forward, as Diem mentioned earlier in the call, we are well positioned for substantial revenues in the fourth quarter and into 2025 in light of our outstanding order balance of $146 million as of September 30. As such, we believe 2024 is lining up to be another year of strong product revenue performance.

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

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.

Should you have a question, please press the star followed by one on your touchtone phone. You will hear a prompt that your hand has been raised. Should you wish to decline from the pooling process, please press star followed by 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 Jyoti Prakash at Edison Group. Please go ahead.

Jyoti Prakash

Hello. Thank you for taking my questions. I have around three to four questions, let me ask them one after the other. It's great to see that the deliveries under the BARDA order for oral TPOXX have started happening in Q4. My question is related to the deliveries of IV TPOXX, which seem to be more protracted in comparison to oral TPOXX. What are the reasons for this? Are there any particular supply chain related constraints? When can we see orders being delivered for IV TPOXX? Secondly, when can we expect the latest order from the Department of Defense to be delivered?

Diem Nguyen

Jyoti, thank you so much for your first question. I will start by first giving you a little context between oral TPOXX as well as the IV. Oral TPOXX is the predominant formulation of the U.S. Government stockpile, and in connection with its delivery activity. The timing and cadence of the order activity is very, very different between the two formulations, whether it's oral or IV. The manufacturing process for IV is much more complex than the oral process for TPOXX with the use of different vendors, as well as some different raw materials.

Given these differences, IV and oral TPOXX are on different schedules, with IV requiring longer manufacturing lead times than oral. Lastly, product deliveries, whether it's IV or oral, are partially dependent on when the customers would like to take delivery. As Dan mentioned, the timing of the oral from the last contract tranche started in 2024 and will continue into 2025.

Jyoti Prakash

Okay, that's helpful. Just on the question on the deliveries under the Department of Defense contract?

Diem Nguyen

I think…

Dan Luckshire

This year.

Diem Nguyen

I said that the deliveries have started already this year and will continue into 2025.

Jyoti Prakash

Okay. Thank you. The second question is related to your international efforts. It's great to see you make your commercial foray into Africa. Just want to understand, since your amendment/agreement of your amendment with Meridian, what kind of traction, opportunities or challenges are you seeing in the international markets?

Diem Nguyen

Thank you. As a general reminder for the broad audience, we amended the Meridian agreement effective June 1, so that we could bring all the international marketing sales in-house except for a few administrative and supportive activities provided by Meridian. This change has given us greater control to meet the needs of our global customers. Since amending the agreement, we have been spending considerable time strengthening and building our relationships with current as well as potential customers around the globe -

all centered around expanding our international business. With the recent sale in Africa at the request of the Ministry of Health of Morocco, we believe our effort is off to a great start. Bringing the effort in-house has definitely enhanced our depth and dialogue with international customers and we expect it will help our ongoing efforts to pursue sales opportunities over the immediate and long-term horizon. We have not experienced any challenges at this point in this transition.

Jyoti Prakash

Perfect. Moving on, it's great to see that you've been licensed a new pre-clinical program. Can you provide us some more details on the deal economics and when can we expect this program to enter clinical studies? How do you plan to develop this as a monotherapy or a combination therapy with TPOXX?

Diem Nguyen

Sure. Thank you for asking. We're extremely excited about the recent in-license of the monoclonal antibody portfolio from Vanderbilt. And we're excited about this opportunity to expand our pipeline and strengthen our capability in the orthopoxvirus space. These antibodies, we believe, have the potential to treat a broad spectrum of orthopoxviruses, which is inclusive of smallpox and mpox, and we would look to develop them from a therapeutic as well as a prophylactic consideration. They've demonstrated promise in pre-clinical models and could potentially be used as a standalone treatment or in combination with TPOXX.

Given our capabilities in clinical development as well as partnerships with U.S. Government agencies, we believe we're best suited to maximize the potential of these therapies in a cost-effective manner. In fact, the DoD has recently funded the development through a third party with monoclonal antibody manufacturer expertise through Phase 1. As we work through the clinical development process, we will keep you posted. It's premature to talk about timing.

Jyoti Prakash

Excellent. I have one final question. There have been recent media reports on some mpox patients being resistant to TPOXX. Can you provide your perspective on these reports and if that's a concern for SIGA?

Diem Nguyen

Thank you for giving us an opportunity to weigh in on some of these reports as it relates to resistance. I always think it's important to think about considerations based on totality of data. I will first start by saying that the preclinical evidence collected to date has shown no resistance in animals treated with TPOXX for an extended timeframe. Additionally, CDC reports document only a small number of drug resistance developing in patients receiving TPOXX. Overall, it remains low, at less than 1% in the patient population. This resistance has been primarily observed in a limited number of immunocompromised patients or those with advanced HIV who have received extended courses of treatment beyond the recommended duration. I think the recent report you're referring to is the October CDC Morbidity and Mortality Weekly Report?

Jyoti Prakash

Yes.

Diem Nguyen

This noted a small sample of patients with mild mpox. Resistance to TPOXX was reported in a few patients. This finding is potentially important and does warrant further investigation to guide future treatment protocols. However, I think it's important to note that the treatment history documentation was not collected to better understand these reports.

Additionally, these reports omit important data related to the total number of specimens tested, patient profiles, as well as treatment timing, making it difficult to reach a conclusion about tecovirimat's efficacy in mpox treatment or overall detection of drug resistance.

It's really important to note that the resistance to smallpox or mpox is less likely to occur compared to COVID-19 or influenza. For example, smallpox and mpox are DNA viruses which mutate less easily than RNA viruses like the viruses that I just mentioned, COVID and influenza. This may contribute to the low levels of resistance observed to date with tecovirimat. I would like to remind everyone that there is no demonstrated tecovirimat resistance to smallpox, and we have not identified that to date.

Jyoti Prakash

Thank you. That's very helpful. That's all the questions I have. Congratulations on the quarter. Thank you.

Diem Nguyen

Thank you.

Operator

Thank you. Ladies and gentlemen, as a reminder, should you have any questions, please press star one. It appears we have no further questions. I will turn the call back over for closing comments.

Diem Nguyen

Thank you so much for dialing in to SIGA's call and for your ongoing interest in our company. We look forward to speaking to you again on our fourth quarter call. Have a good rest of the evening.

Operator

Ladies and gentlemen, this concludes your conference for today. We thank you for participating and we ask that you please disconnect your lines.