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SIGA Technologies, Inc.
Q2 2024 Earnings Call

EDITED TRANSCRIPT

Event Date: August 1, 2024

SIGA Technologies, Inc. – Q2 2024 Earnings Call on August 1, 2024 (edited)

CORPORATE PARTICIPANTS

Diem Nguyen, *Chief Executive Officer*

Daniel Luckshire, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Soo Romanoff, *Edison Group*

PRESENTATION

Operator

Welcome to 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 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...

Diem Nguyen

Good afternoon, everyone, and thank you for joining today's call and review of our business results for the second 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 am pleased to report that SIGA has continued to generate product revenues that outpace revenues in the comparable periods last year. Product revenues for the three and six months ended June 30, 2024, were $21 million and $45 million, respectively. This surpasses product revenues of $1 million and $7 million, respectively, for those periods in 2023.

These strong results are reflective of SIGA's staying power.

Our capital management activity over the past several years, including substantial special cash dividends, reflects, and has been made possible by, this strong long-term performance. Our focus

on long-term performance is critical due to the nature of SIGA's business and the inherent quarter-over-quarter fluctuations.

We believe the financial results for the first six months of 2024 support an important positive long-term trend. Our sales reflect a diverse mix of oral TPOXX deliveries to the U.S. Strategic National Stockpile, or SNS, the U.S. Department of Defense, and 11 international customers, as well as IV TPOXX deliveries to the SNS. Looking ahead, we anticipate a continued diversification of our revenue base will be important for maximum long-term performance.

Consistent with what we said last quarter, we expect 2024 to be another year of strong product revenues. As a reminder, our 2023 product revenues were the highest achieved over the past five years. Two weeks ago, the U.S. Government exercised its procurement option under the 19C BARDA contract for the delivery of approximately $113 million of oral TPOXX. We plan to work with the U.S. Government on the timing of delivery, and currently anticipate deliveries will begin within the next 90 days.

We foresee a meaningful portion of this order will be delivered before year end, supporting our expectation that product revenues will again be substantial this year. It is our view that this award illustrates the U.S. Government's belief that smallpox continues to be a threat. It also demonstrates its ongoing commitment to maintaining a robust stockpile of smallpox antivirals to help ensure the health security of the American people - an issue that has consistently garnered bipartisan support.

TPOXX has a strong safety profile, based upon preclinical safety and toxicology data, Phase 3 clinical data in healthy volunteers, as well as clinical observations. Over 1,500 mpox patients have been enrolled in clinical trials to assess the efficacy of TPOXX for the treatment of mpox, utilizing TPOXX and its matching placebo provided by SIGA to trial sponsors at no cost. As a result, we anticipate it would be the preferred antiviral treatment in the event of an outbreak.

Our attention is now firmly set on securing the next procurement contract with the U.S. Government. Our team continues to be actively engaged with a broad range of government officials as we prepare for a request for proposal, or RFP, which can be issued by Administration of Strategic Preparedness and Response at any time. While we wait for this next RFP, there are a number of factors that give us confidence.

First, earlier this year, Congress approved the budget for the U.S. Government which includes another substantial increase in the federal budget for countermeasures, including the SNS. This funding outcome underscores the government's ongoing commitment to preparedness and response.

Second, the current public health environment, including the Clade 1 mpox outbreak in the Democratic Republic of the Congo, or the DRC, highlights the heightened pandemic risk and continued need for nations to be response-ready. This includes the timely procurement of effective therapies, like TPOXX.

Third, we have a long-standing partnership with the U.S. Government to provide a critical countermeasure against one of the world's most dangerous biothreats. As a reminder, smallpox is one of only six diseases considered a Category A threat by the CDC, and herd immunity is waning

among our population. In fact, TPOXX was among the first novel small molecule therapies delivered to the SNS under Project BioShield, and was developed in collaboration with BARDA.

All in all, based on our conversations with government officials as well as other SNS contracts to procure medical countermeasures, we are confident that the government is receptive to a new, long-dated contract, most likely between 5 and 10 years, and the aggregate value of this contract should surpass the aggregate value of our current contract, under which most options have now been exercised. As a frame of reference, the current 19C BARDA contract signed in 2018 has a procurement value of $546 million.

This is an exciting time for SIGA. As I said earlier, the health and security of Americans is an issue that continues to garner bipartisan support. So, while we await the receipt of this next RFP, we are keeping our focus on our longer-term goals. We have the financial strength to advance our business with current and potential customers outside the U.S. while remaining ready to collaborate with the U.S. Government once it initiates the RFP process.

Dan will provide further details on our financial position shortly. In summary, our balance sheet is robust with no debt, our cash flow remains strong, and we have exercised prudent cash management. This allowed us to recently pay a special cash dividend in April.

Moving on, we've also made progress in several other key areas.

In April, we announced an amendment to our international promotion agreement with Meridian Medical Technologies, under which SIGA began driving promotional activities outside the U.S. for oral TPOXX, starting June 1. Since then, our team has strengthened relationships with key global customers, and we are confident these efforts will lead to growth over time.

In June, we announced an agreement to sell TPOXX to the member states in the Association of Southeast Asian Nations. This agreement is a foundational step in a highly populated region for strong collaboration in the future.

In Japan, we continue to have productive conversations with our partner, Japan Biotechno Pharma, and regulators on the new drug application for TPOXX for the treatment of smallpox, mpox, cowpox, and complications due to the vaccinia virus. Based upon the standard review timeline for a new drug application, we expect a final regulatory decision by early next year. If approved, we anticipate that TPOXX will be placed in national stockpile, ready for deployment in the event of an outbreak.

We continue to pursue the expansion of TPOXX approvals in new indications, such as PEP and mpox, and formulations.

First, on PEP, as I've stated before, we believe that TPOXX has the potential benefit against smallpox in a post-exposure prophylaxis. Currently, much of our work has been focused in the completed TPOXX-JYNNEOS safety and immunogenicity trial to evaluate TPOXX when administered together with JYNNEOS. As a reminder, this trial was requested by the FDA because of the likely use of TPOXX and JYNNEOS together in the event of an outbreak. The trial was designed to test this drug-vaccine combination to ensure there would be no impact to patient safety or vaccine immunogenicity. As a reminder, the data from the trial is supportive of the safety objective.

Regarding immunogenicity, we are continuing to work with the CDC, in consultation with the FDA, to complete an analysis of the samples collected to support the immunogenicity objective. At the same time, we are working on our supplemental NDA submission and targeting submitting it within the next 12 months.

Turning to the ongoing mpox trial, the trial sponsors continue to make significant progress. The NIAID PALM 007 trial in the DRC has now completed enrollment. We anticipate release of topline data in the coming weeks. The DIAID STOMP trial has seen considerable growth with 515 patients enrolled as of July, up from 350 reported from our last call.

Mpox remains a global threat, particularly in the DRC where cases continue to rise. To support investigators and health agencies, in 2022 we donated over 500 courses of TPOXX capsules and its corresponding placebo for the randomized clinical trial PALM 007. Recently, we donated another 100 courses to ensure patient access continues during data analysis. We're also working to support broader access programs in Africa.

Additionally, the U.S. Government has distributed approximately 40,000 courses of TPOXX in response to the 2022 mpox outbreak through the CDC's compassionate use program. We continue to monitor the situation actively, providing assistance, when possible, to achieve the best possible outcomes for mpox patients.

In summary, our company is strong, profitable, and well-positioned for the future and supported by the following four pillars.

Number one, we have a well-crafted strategy that is yielding results.

Two, we have a prudent approach to capital management, which has afforded us the opportunity to pay significant special cash dividends.

Three, we have a valuable TPOXX franchise that fulfills a critical requirement established by the U.S. Government to ensure the country is prepared in the event of a natural, accidental, or intentional outbreak.

And four, we have a resilient team with proven operational capabilities who are executing on our strategy with urgency and effectiveness.

Combined, we believe these pillars will enhance shareholder value over time and improve public health.

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

Daniel Luckshire

Thanks Diem.

As noted earlier in the call, SIGA's product revenues for the three and six months ended June 30, 2024 were $21 million and $45 million, respectively, which surpass product revenues of $1 million and $7 million, respectively, for the comparable periods last year.

Product revenues for the quarter were primarily related to approximately $18 million of IV TPOXX sales to the U.S. Government. For the six months ended June 30, 2024, product revenues reflect a diverse mix, including approximately $15 million of oral TPOXX sales to the U.S. Government under the 19C contract, approximately $11 million of international oral TPOXX sales to 11 countries, approximately $1 million of oral TPOXX sales to the U.S. Department of Defense, and the previously mentioned approximately $18 million of IV TPOXX sales to the U.S. Government.

In addition to product revenues, the Company had Research and Development revenues of approximately $1 million and $3 million for the three and six months ended June 30, 2024, respectively.

Pre-tax operating income, which excludes interest income and taxes, was approximately $1 million for the three months ended June 30, 2024. For the six months ended June 30, pre-tax operating income was approximately $12 million. In comparison, there was a pre-tax operating loss for the three and six months ended June 30, 2023, of approximately $5 million and $7 million, respectively.

Net income for the three months ended June 30, 2024, was approximately $2 million. For the six months ended June 30, net income was approximately $12 million. In turn, fully-diluted income per share for the three months ended June 30, 2024, was $0.03 per share and for the six months ended June 30, fully-diluted income per share was $0.17

At June 30, 2024, the Company continued to maintain a strong balance sheet, with a cash balance of approximately $107 million and no debt. On April 11, SIGA paid the previously disclosed special cash dividend of $0.60 per share, which amounted to an approximately $43 million payment to shareholders.

Looking forward, as Diem mentioned earlier in the call, we are working diligently to continue our positive momentum. 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

Thanks Dan. Leveraging our achievements from 2023 and the positive momentum generated so far this year, we believe SIGA is poised for continued growth and innovation. We remain focused on advancing our strategic goals, including securing a new contract with the U.S. Government, optimal capital management, and enhancing our TPOXX franchise. We are confident this will deliver value to our patients, partners, and shareholders over time.

Now, I would like open the call to Q&A. Operator…

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 the one, on your touch-tone 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 two. If you are using a speaker phone, please lift the handset before pressing any keys. One moment, please, for your first question.

The first question comes from Soo Romanoff. Soo?

Soo Romanoff

Hi. Sorry, I had some technical difficulties here.

Thank you for taking my question. Congratulations on another strong quarter. I have a multi-part question, and these are mostly just to garner a little more color. It sounds like you've delivered—it was nice to hear the $113 million BARDA exercise for the remaining part of oral TPOXX come across. It sounds like you're going to deliver meaningful portion in 2024, despite the manufacturing bottleneck. Any more color on the timeline would be helpful.

The second part would be, could you provide a sense of when BARDA will exercise the remaining $26 million IV TPOXX? I believe the July '23 IV TPOXX order was yet to be delivered.

The last part is, could you provide an update on the U.S. Government negotiations? I believe we were looking at some kind of recurring arrangement.

Diem Nguyen

Thank you, Soo. If you can hear me, I'm going to try to tackle your question in three parts.

The first question relates to the recent BARDA exercise of our remaining option and when do we anticipate the delivery. What I would say here is that we've been proactively coordinating with our supply team in preparation for the U.S. Government's exercise of this option under the current BARDA contract. And we are working with our partners to produce and deliver oral TPOXX on a schedule that makes sense for our customer, the U.S. Government. We are confident in our ability to deliver and expect to start shipping within the next 90 days, with a meaningful portion of this to be delivered this year. We are collaborating with the U.S. Government to determine optimal timing and, therefore, cannot be more specific at this time.

As it relates to your second question, you had asked about the IV TPOXX option. Just to give you a little bit of background, the $18 million that was discussed today of the IV TPOXX sales in the second quarter relates to the 2022 order. Once we finish this 2022 order, we will then coordinate with the U.S. Government and our supply chain on the timeline for producing and delivering on the 2023 order. Based on what we know today, we do anticipate that BARDA will exercise the final $26 million option in 2025.

I guess the last question that you had, Soo, was an update on the U.S. Government negotiations. As we mentioned during our prepared remarks, we have been having discussions with a broad range of government officials. From these conversations, there is a clear bipartisan support in helping to ensure the health security of the American people. And given the increased geopolitical risk globally and the mpox outbreak in the DRC, we are prepared to respond when ASPR is ready for the start of that RFP process.

As mentioned, our aim is to secure a long-term contract with more regular purchases, and that this contract reflects the value of TPOXX that's provided today as well as in the future. We do believe the U.S. Government is open to a long-term contract, potentially up to 10 years, and one with a higher aggregate value than the 2018 contract.

Soo Romanoff

That's great. If I can ask one more question, if you don't mind.

Diem Nguyen

Sure.

Soo Romanoff

It's good to see there's a lot more interest, I mean with the recent ASEAN Country agreement for oral TPOXX. We touched on this a little bit, but any clarity on the size, timelines would be helpful. Then also, I know you're working with Meridian. Any kind of color on the fee structure economics for this new order would be kind of nice too.

Diem Nguyen

Sure, I'll talk about the ASEAN agreement, and, Dan, you can highlight in terms of the Meridian economics.

First, I want to really highlight that we are incredibly pleased with this agreement, which was signed in June. This agreement further advances our strategy to expand access to TPOXX to even more international markets. Asia is a strategic region for SIGA. This contract represents an important step to growing orthopoxvirus preparedness in the Asia region and does establish a footprint in a highly populated region. It also sets the groundwork for additional activity for the future.

As we noted in our June release, we did receive $3 million order from a new customer in the ASEAN region. We believe this is the first important step to larger collaboration as the ASEAN member states together represent a population of over 600 million people with a GDP of over $3.6 trillion. We have not disclosed the financial terms to date, however, as we have emphasized, we're quite optimistic with this collaboration.

Dan, would you like to talk about the Meridian amendment?

Dan Luckshire

Yes, certainly. We disclosed the original amendment earlier in the early June timeframe. With that, what it did was it really allowed us to take over ownership of the international marketing and relationships. With the amendment, the goal was to ensure a very, very smooth handoff for the next period of time. So with that, there were some key countries and regions that we wanted to ensure, especially for the handoff, that were really concentrated in Europe, Australia, and Japan. So it's much more limited in scope than the prior arrangement. In addition, the fee is materially lower than

the original fee. We did not disclose the original fee, but it is materially lower, and the current fee is in the high single digits.

Soo Romanoff

That's great. If you don't mind, if we can touch on the new mpox strain in the DRC. I know you touched on this also. It seems like the governments are pretty alert now. Are we getting more inquiries from international markets? Then, it sounds like the mpox trials are progressing, and if we can expect the U.S. filing to made soon?

Diem Nguyen

Yes, maybe I can take that and I'll start with just more inquiries in the international market.

Clearly, TPOXX, or tecovirimat, has the benefit of being an antiviral treatment for smallpox, which is quite important from the consideration from a public health security perspective and, as such, driving stockpile considerations from a preparedness perspective.

The mpox outbreak in 2022 heightened the awareness of orthopox threats and has driven certainly international recognition as well as the need to, one, address mpox outbreaks at a targeted level, but then a broader long-term consideration from a policy perspective from a smallpox stockpile.

So while they're a bit independent when you think about how to look at the volumes and the preparedness requirements, they are intertwined in the consistency of increased orthopox threats, whether that's naturally occurring, such as mpox, or whether it could be potentially intentionally driven from a smallpox outbreak perspective.

In particular, from 2022 to where we are today, we are facing another new mpox strain in the DRC, and we also share the concern of not only the rising number of mpox cases in the DRC, but also the increased prevalence of the Clade I strain, which is much more lethal than Clade II.

Mpox cases have persisted over the past two years, including in the U.S., particularly in people who are not vaccinated or who have only received one dose of JYNNEOS. As a quick reminder, mpox cases were concentrated in Africa in 2022 before spreading globally. This highlights the importance of monitoring case activity in Africa when thinking globally. The mpox clinical trials, as mentioned, are progressing well, and we look forward to the topline results in the PALM 007 clinical trial in the DRC in the coming weeks. We also noted the STOMP trial has enrolled roughly 515 patients as of July. This is a substantial increase from the 350 patients noted in our last call, which is also highlighting the increased cases that we're observing. Assuming the positive data, we will work with our trial sponsors, with the goal of filing an mpox supplemental NDA as early as 2025. We're monitoring this situation quite closely, Soo.

Soo Romanoff

Yes, that's great. Okay, well thank you for the answers, and great quarter, again. Congratulations.

Diem Nguyen

Thank you.

Operator

Once again, if you do want to ask a question, press star, followed by the one, on your touch-tone phone.

There are no further questions at this time. I'd now like to return the call back over to Diem Nguyen, CEO. Diem?

Diem Nguyen

Thanks, Atif. I'd like to thank everyone for making time to join us on today's call and for the ongoing interest in SIGA. We look forward to speaking again in our third quarter call. Have a good rest of the evening.

Operator

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