
# SIGA Technologies

## Third Quarter 2023 Earnings Call

## November 8, 2023

## CORPORATE PARTICIPANTS

**Phil Gomez,** *Chief Executive Officer*

**Dennis Hruby,** *Chief Scientific Officer*

**Jay Varma,** *Chief Medical Officer*

**Dan Luckshire,** *Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

**Pooya Hemami,** *Edison Group*

## 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 from the forward-looking statements. SIGA does not undertake any obligation to update publicly any forward-looking statements to reflect events or change circumstances after this call.

For 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, 2022, and its subsequent reports on Form 10-Q and Form 8-K.

I would now like to turn the conference over to Phil Gomez, Chief Executive Officer. Thank you. Please go ahead.

**Phillip Louis Gomez**

Thank you for taking the time to join today's call. Today, I'm joined by Dennis Hruby, our Chief Scientific Officer; Jay Varma, our Chief Medical Officer; and Dan Luckshire, our CFO. We are pleased to have this opportunity to provide an update to our shareholders. We'll then be happy to take questions.

I'd like to start this call by highlighting key financial targets for 2023. We expect orders for oral and IV TPOXX to be approximately $164 million in 2023, with a substantial percentage of these orders to be delivered in 2023. As such, as previously disclosed, we are targeting 2023 pre-tax operating income of between $90 million and $100 million based on the timing of deliveries that are currently being coordinated among the Company, our supply chain, and our government customers.

Target pre-tax operating income for 2023 is based on the following target revenues: approximately $113 million of revenues from fourth-quarter deliveries of oral TPOXX to the U.S. Strategic National Stockpile; approximately $5 million of revenue from fourth-quarter deliveries of oral TPOXX to the U.S. Department of Defense; $15 million to $18 million of revenues from fourth-quarter international deliveries of oral TPOXX to European countries in connection with the recently announced HERA joint-procurement framework contract; and up to $15 million of revenue from fourth-quarter deliveries of IV TPOXX to the U.S. Strategic National Stockpile.

To the degree that any target deliveries and related target revenues and pre-tax operating income do not occur in the fourth quarter of this year due to any timing constraints in connection with our customers or our packaging vendor, we expect that such deliveries and revenues would occur in January of 2024.

In particular, one thing that could impact the timing of deliveries between fourth-quarter 2023 and January 2024 is the packaging of final drug product. This step of the process has been taking longer this year than in prior years and longer than expected so far this year. Needless to say, we have been in daily contact with our packaging vendor, and we continue to work together on getting packaging done as soon as possible and with an eye toward making the remaining target deliveries in 2023.

Beyond 2023, we will continue to execute on our strategic plan to maximize growth opportunities.

I will now ask Dennis to provide an update on the PEP and mpox programs for oral TPOXX. Dennis?

**Dennis Hruby**

Thanks, Phil. I'd like to provide a summary of the strategy for PEP as we received some questions on this topic after the last investor call.

Based on the studies and trials that have been conducted, we believe TPOXX will work for PEP. The FDA has not asked for any additional studies to prove the efficacy of TPOXX for PEP. They have asked for extended safety data in humans for treatment for 28 days, which we completed.

In a smallpox outbreak, TPOXX would likely be used in combination with a smallpox vaccine. The JYNNEOS + TPOXX study we will discuss is designed to solely evaluate if TPOXX interferes with the generation of an immune response to the vaccine.

Let me now provide a quick recap of what was noted in the last investor call.

Earlier this year, the Company met enrollment targets for both the immunogenicity trial and the expanded safety trial. For the expanded safety trial, as expected, the clinical trial result did not show any drug-related serious adverse events. For the JYNNEOS + TPOXX immunogenicity trial, as a quick reminder, the goal of this trial was to show that TPOXX did not reduce the immune response to the vaccine. This is supplemental, and separate, to our current approval for the treatment of smallpox. In the preliminary analysis of the trial data performed by our CRO, the results did not show a meaningful difference between the immunogenicity of those who received the JYNNEOS vaccine while on placebo, compared with those who received the JYNNEOS vaccine while on TPOXX, which is consistent with what we expected.

However, as noted on the last investor call, the CRO results indicate that a number of volunteers that had measurable immune response to the JYNNEOS vaccine in both placebo and TPOXX groups was lower than expected. Given that this result (1) would prevent "non-inferior" statistical determination from being the primary endpoint as originally planned, (2) is unexpected, and (3) is scientifically odd, we've been investigating the CRO results over the past series of months.

Since the last investor call, in addition to conducting many other investigations, we sent a subset of the JYNNEOS + TPOXX samples to our colleagues at CDC who performed their validated PRNT analyses on them. These samples showed the expected immune responses. As such, we're now working on getting the entire set of samples re-analyzed, and in parallel, working toward a supplemental NDA submission in 2024. We are grateful to our colleagues at CDC for this collaboration and are pleased to have identified a path forward.

In terms of getting the maximum and most timely benefit from the immunogenicity trial in the context of stockpile expansion conversations with the government, we believe the steps taken over the past series of months is worth the extra time and effort to ensure the highest quality data.

To be clear, we're working on finalizing the immune response levels of volunteers in the vaccine. The analyses are not about the efficacy or safety of TPOXX, nor are they about TPOXX's impact on those individuals who are showing an immune response.

To reiterate contextual comments made on the prior investor call, we believe that in regard to the PEP program, the totality of the studies and trials that have been conducted, including the immunogenicity trial as well as previous animal challenge experiments and clinical trials, are supportive of the use of TPOXX for PEP, pending discussions and review with the FDA. In the case of an orthopoxvirus epidemic, be it mpox or smallpox, use of TPOXX for PEP will be important to reduce the morbidity and mortality in the population.

Shifting gears, let me also provide an update on the current mpox trials involving TPOXX, which include five randomized controlled trials as well as multiple observational studies. As a general comment, these studies continue to enroll patients and collect data.

To provide a couple of specific data points, in Africa, as of October 19, the NIAID PALM trial being conducted in the DRC enrolled 314 patients, a big jump from the 188 patients noted in the last investor call. In the NIAID STOMP trial, as of October 31, there were 169 patients. The increase in patient numbers in the aforementioned trials highlights that case counts continue to accumulate, especially in Africa.

Importantly, it also provides a glimpse to the overall global health risk posed by orthopoxviruses. Jay will provide further comments on mpox and orthopoxviruses. Before I turn the call over to Jay, I'd like to provide a quick update on our pediatric program for TPOXX.

Having completed a clinical trial that demonstrates equivalence of drug exposure in volunteers given the TPOXX oral capsules or the powder for reconstitution liquid formulation, we are commencing advanced development. We've chosen a scale-up manufacturer to prepare clinical supplies, and we're in the process of designing a clinical development program, which would support licensure. We consider this program to be an exciting path for potentially providing protection to the pediatric population.

At this point, I'll turn the call over to Jay.

**Jay Varma**

Thanks, Dennis. As Phil and Dennis have mentioned on this call and prior calls, mpox preparedness and more broadly orthopoxvirus preparedness are essential from a public health perspective. As such, I am glad to have joined SIGA as an officer.

As the Chief Medical Officer, I am responsible for leading Medical Affairs. This means that I am providing support for the overall goals of SIGA, and in particular, in leading our efforts to build broader awareness of the risk and public health impact of smallpox, mpox, and other orthopoxvirus outbreaks and to promote

strategies in procurement and treatment that can support the highest levels of public and individual safety. I will represent SIGA in engagement with leaders from patient advocacy, medical organizations, professional societies, global and regional health agencies, and other public health and defense organizations around the world.

As background, one of the key reasons that I was highly interested in joining the SIGA team was that I believe my experience and skills are a good fit with SIGA. As a quick introduction, let me provide a brief summary of my professional background. I'm a physician and epidemiologist who has led epidemic responses, developed global and national policies, and led large-scale programs that have saved hundreds of thousands of lives in China, Southeast Asia, Africa, and the United States.

From 2001 to 2021, I worked for the U.S. Centers for Disease Control and Prevention with postings in Atlanta, Thailand, China, Ethiopia, and New York City. From April 2020 to May 2021, I served as a principal scientific spokesperson and lead for New York City's COVID-19 response.

Before I turn the call over to Dan, I would like to make some brief remarks in connection with the smallpox and mpox threat. The risk of these threats is growing with many public health officials arguing that we have entered a new age of pandemics. With development, urbanization, migration, and climate change, humans are interacting with animals in the environment in new ways, accelerating the risk of new diseases spilling over into humans.

Humans are also increasingly conducting research on pathogens using novel techniques in biology. This increases the risk of the accidental spillover of a dangerous pathogen in a lab or, more worrisome, the deliberate release of a dangerous pathogen as an active bioterrorism. Specifically, with respect to smallpox, this threat has increased. Armed conflict around the world, particularly involving countries that are believed to have developed biological weapons, increases the likelihood that a rogue actor or nation could deliberately release the virus.

For mpox, while cases have declined globally since the 2022 pandemic, outbreaks continue to occur in East and Southeast Asia and Latin America. Particularly concerning are the high and rising cases in the Democratic Republic of Congo, involving a subtype of the virus known as Clade 1, that causes more severe illness and death than the subtype that circulated around the world during the recent pandemic.

In the May 2023 issue of the Medical Journal, the *Lancet*, several prominent public health experts flagged their concern that this subtype is more similar to smallpox and that failure to stop transmission in Central Africa could lead to a far worse mpox pandemic than the 2022 one. In response, as detailed by Dennis, we are working closely with NIH and other health agencies on randomized clinical trials to demonstrate whether TPOXX is safe and effective for treating mpox in Africa, the U.S., and other parts of the world. I'm working with the team to get the best possible results from a public health and Company perspective.

At this point, I would like to turn the call over to Dan for our financial update.

**Daniel Luckshire**

Thanks, Jay. For the three and nine months ended September 30, 2023, SIGA's revenue was approximately $9 million and $23 million, respectively. For the third quarter, approximately $8 million of revenue relates to international sales of oral TPOXX and approximately $1 million relates to research and development activity. In connection with the international sales of oral TPOXX, it included a sale to a first-time customer.

For the nine months ended September 30, approximately $15 million of revenue relates to product sales and supportive activities and approximately $8 million of revenue relates to research and development

activity. In connection with product sales, $5 million of the sales were to the U.S. Department of Defense and approximately $9 million of sales are international.

Pre-tax operating loss, which excludes interest income and taxes, was approximately $1 million for the three months ended September 30, 2023. For the nine months ended September 30, pre-tax operating loss was approximately $8 million. Net loss for the three months ended September 30, 2023, was less than $1 million. For the nine months ended September 30, net loss was approximately $4 million. In turn, fully-diluted loss per share for the three months ended September 30 was $0.01 per share, and for the nine months ended September 30, fully-diluted loss per share was $0.06.

At September 30, 2023, the cash balance for the Company was approximately $71 million. For the first nine months of the year, SIGA spent approximately $43 million on capital management with a special cash dividend of approximately $32 million and share repurchases of approximately $11 million.

As noted by Phil earlier in the call, we are targeting 2023 pre-tax operating income of between $90 million and $100 million based on the timing of deliveries that are currently being coordinated among the Company, our supply chain, and our government customers.

Target pre-tax operating income for 2023 is based on the following target revenues: approximately $113 million of revenues from fourth-quarter deliveries of oral TPOXX to the U.S. Strategic National Stockpile; approximately $5 million of revenues for fourth-quarter deliveries of oral TPOXX to the U.S. Department of Defense; $15 million to $18 million of revenues from fourth-quarter international deliveries of oral TPOXX to European countries in connection with the recently announced HERA joint-procurement framework contract; and up to $15 million of revenues from fourth-quarter deliveries of IV TPOXX to the U.S. Strategic National Stockpile.

To the degree that any target deliveries, and related target revenues and pre-tax operating income, do not occur in the fourth quarter of this year due to any timing constraints in connection with our customers or our packaging vendor, we expect that such deliveries, and revenues, would occur in January of 2024.

This concludes the financial update. At this point, I'll turn the call back to Phil.

**Phillip Louis Gomez**

Thanks, Dan. Before we open the call for Q&A, I'd like to make a few concluding remarks.

First, mpox continues to be a worrisome disease with significant impact and potential to grow. As Dennis and Jay have highlighted, we continue to see cases even though the global outbreak has receded.

Second, our ongoing international sales growth initiative is progressing in a value-creating manner, as evidenced by the recently announced pan-European joint procurement contract. We have a solid base of international customers, through which we continue to pursue additional customers as well as follow-on orders.

Third, the PEP-based development program continues to represent a growth initiative in that it may provide scientific and regulatory support for any stockpile expansion. The team is working hard to complete the follow-on immunogenicity testing and file for FDA approval of PEP.

Fourth, we continue to be focused on transitioning our U.S. government contract to a long-term SNS contract that focuses on appropriate size requirements for the TPOXX stockpile as well as smoothing the annual deliveries, which would be critical to supply chain planning and provide a higher degree of financial predictability.

This concludes our prepared remarks and we will now begin the Q&A session.

**Operator**

Thank you.

(Operator Instructions)

Your first question comes from the line of Pooya Hemami from Edison Group. Please go ahead.

**Pooya Hemami**

Yes, hello, thank you for taking my questions. I have a question on the HERA contract. You expect about $18 million worth of orders over the next two months. Given that there are several other EU nations under the guidance of HERA, do you expect or do we expect to receive incremental countries or other countries that are not of those 13 right now?

**Phillip Louis Gomez**

Yes, thanks for the question. We certainly do. This essentially provides a contract vehicle with a price that's been negotiated for all EU countries, and this represents the first order. There is pricing that is based on volume. There's an incentive to pool orders before they go forward. But, the vehicle has the concept of a quarterly review with customers and the ability to put in orders on a quarterly basis. I think that will be based on how many come in and the volume to make sure they feel they're getting the right volume discounts that they want to get. But in essence, this is broadly a hunting license as well because now we can go to countries that haven't purchased and say there's a vehicle to do this. The terms have been negotiated; the price has been negotiated. We do feel like this is a nice step.

I would say, our understanding is it's the first vehicle that has been ever put in place in Europe for chemical biological products like this. We're excited that we've opened up this vehicle and we look forward to talking now to customers directly about follow-on orders. Thank you for the question.

**Pooya Hemami**

Thank you. As a follow-up to that, and on your last remarks, do you envision that this arrangement with HERA will develop into something similar to what you have with BARDA which covers a certain percentage of the U.S. population in theory? What kind of upsell venture do you foresee here?

**Phillip Louis Gomez**

Yes. The mechanism that HERA is using is not the same as BARDA. In the U.S., the U.S. government determines what a stockpile size should be. They then procure product to meet that stockpile size on behalf of the entire U.S. population. It's evolving in Europe. But right now, HERA does not set a target for all of Europe. They do emergency small procurements. People may remember last year, they did do a direct procurement for roughly $10 million to get some initial courses. But really, what they're doing in this vehicle is allowing countries to procure under it, but each country ultimately is determining what their budget is, what they're doing to start stockpiling on their behalf.

There have been broader discussions at the European Commission level to set up targets, central funding. That just hasn't gotten to the point yet where they're making targets, but we're encouraged that there's a lot more conversation in Europe than there was historically and certainly, as evidenced by this initial order under this contract, there is some opportunity here that we look forward to pursuing.

**Pooya Hemami**

Okay. Thank you very much.

**Operator**

Thank you. Your next question comes from the line of Paul Saunders from Hatch Capital. Please go ahead.

**Paul Saunders**

Yes, hi guys. Thanks for taking my question. First question is just on the buyback. I noticed that you didn't buy any shares back this quarter. I was just curious if you had any thoughts or commentary on not buying any shares back.

**Phillip Louis Gomez**

Hey, Paul, thanks for the question. Good to hear your voice. As we've said in our conference calls, any buyback decision is a multiyear and certainly multifaceted set of circumstances around cash flow, orders, other opportunities, and the Board and Management review that. We don't comment on specific quarters or buybacks. But as Dan highlighted, we did have the special dividend and the $11 million purchase. We've certainly been active this year in capital management, but we don't comment on quarter-by-quarter buying decisions, but I appreciate the question.

**Paul Saunders**

Yes, and one more for me, if you don't mind. Just a question on the inventory. I know it sounds like this delivery got pushed back because of, it sounds like packaging issues. I know it's inflated due to that. But just running the rough math, if that were fully finished, it looks like it's like 1.5 million courses of inventory. I'm just curious, that's obviously a lot more than what you're going to deliver in the next quarter or two. Just, can you provide any color on that inventory build in excess of what you're going to deliver this upcoming quarter?

**Phillip Louis Gomez**

Yes, so for those that may not know, the cycle time for making our product is certainly, given normal scheduling and proactive scheduling of batches and manufacturing, we have four different manufacturers, It takes well over a year to go through the cycle time of our product. With BARDA, we have pretty good visibility into how that replenishment is going to go. Historically, we had a long lead time, but we are now at a more mature place in our business where we want to make sure that we're able to have a responsive supply chain that doesn't start from zero, but may have targeted active pharmaceutical ingredient in inventory. If we have an opportunity for a sale, we're able to translate that into product in months as opposed to over a year.

You will see, in general, an increase on our balance sheet of inventory that we manage to make sure, if we have an opportunity to accelerate orders with a customer, we can do that. If we ever had a disruption in our supply chain, we'd be ready to do that. We have a lot of flexibility given the stability of our API. As you point out, we do have a bolus that's getting ready for a large delivery to BARDA. We also anticipate next year, as we've said many times, an expiry schedule that will have another $113 million option that would be exercised, and another IV option. We're also building inventory to make sure we're ready for those orders, not just the next quarter.

**Paul Saunders**

Yes, that makes a lot of sense. I appreciate that. If you don't mind, just with the—I assume it was the packaging, why that option exercise didn't get to (inaudible) this quarter. Can you also provide any more color on what happened there with the packaging and maybe how to avoid that in the future?

**Phillip Louis Gomez**

Yes, it's a great question, Paul. We work with a lot of service providers. As we said, we haven't run into any problems, per se, but it's just taken longer to get into those facilities, get it packaged, and get it out. We certainly planned in advance for that, but then we have a sprint once we get the order and have to do the packaging.

Historically, that's actually been an area that's gone very smoothly and rapidly. It just turns out, this year we've run into delays there, not any technical challenges, simply delays. I can assure everyone our team has been working really hard to find ways to make sure we hit the target, but we wanted to highlight that as the challenge that we're focused on right now.

**Paul Saunders**

Sounds good. Thanks, Phil.

**Phillip Louis Gomez**

Thanks, Paul.

**Operator**

Thank you. There are no further questions at this time. Please proceed.

**Phillip Louis Gomez**

I'd like to thank everybody for their time today. We really appreciate the update and look forward to talking to you again soon. Thank you, Operator. Have a good day, everybody.

**Operator**

Thank you. Ladies and gentlemen, that does conclude our conference for today. Thank you all for participating. You may all disconnect.