SIGA Technologies, Inc.

Second Quarter 2025 Earnings Call

Event Date: August 5, 2025

CORPORATE PARTICIPANTS

Diem Nguyen, *Chief Executive Officer*

Daniel Luckshire, *Executive Vice President, Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Jyoti Prakash, *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 of 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, 2024, 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 2025.

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.

At the midpoint of 2025, I'm pleased to share that SIGA continues to make steady progress as we advance our strategic initiatives. The evolving global landscape calls for agility and focus, and our team remains deeply committed to strengthening our role in the global health security and delivering enduring value to our shareholders.

In the second quarter of this year, we achieved two important positive results: significant product revenues and a significant increase to development funding under the BARDA 19C contract. In the quarter, product revenues totaled approximately $79 million, comprised of $53 million of oral TPOXX and $26 million of IV TPOXX delivered to the U.S. Strategic National Stockpile, or SNS. These deliveries fulfilled the $70 million of orders outstanding at year-end 2024.

At the end of the second quarter, there were approximately $26 million of remaining outstanding orders from the U.S. Government. This outstanding balance relates to the March 2025 U.S. Government exercise of an option under the 19C contract to procure an additional $26 million of IV TPOXX. We noted this option exercise during our last investor call and expect to deliver this order in 2026.

Also, during this quarter, we received commitments from the U.S. Government to provide $27 million of incremental development funding. This increase in development funding occurred in two buckets. In April, the government modified the 19C contract by adding $14 million in funding to support manufacturing activities, which we expect to occur over the next two to three years. Most recently in June, the government committed to an additional $13 million of development funding to further support the pediatric program.

We believe these recent actions surrounding IV TPOXX - in procurement and additional manufacturing support - and with respect to the pediatric program, reflect the continued importance of maintaining a full complement of TPOXX formulations in the stockpile as treatment options for smallpox.

Maintaining both oral and IV formulations ensures flexibility in response strategies, as the IV formulation is an important alternative for those who are unable to swallow capsules. Given the severity of smallpox, we view these investments as a strong signal of the United States Government's continued commitment to national health preparedness and recognition of the critical role antivirals play. We're proud to support these efforts.

Looking ahead beyond our current 19C contract, we continue to engage constructively with the U.S. Government. Our goal remains clear: to establish a new comprehensive long-term agreement that reflects the value of TPOXX. Such a framework will not only strengthen the nation's bioterrorism preparedness, but also advance our collective commitment to global health security and public health resilience.

As I've highlighted during prior calls, antivirals play a critical role alongside vaccines—treating individuals who are unvaccinated or who may not benefit from vaccination. With rising threats from emerging infectious diseases and bioterrorism, this dual approach is increasingly essential. In a comprehensive preparedness plan, strategic stockpiling of medical countermeasures is critical to ensure a rapid response in a crisis.

Importantly, given our long-standing partnership with the U.S. Government and our government's demonstrated commitment to proactive biodefense, we remain prepared to respond to an RFP when issued and to complete a procurement agreement in an efficient manner.

Internationally, we have been engaging with stakeholders on the critical role of biodefense in shaping resilient health security frameworks. Strategic stockpiling, supported by multi-year funding dedicated to crisis preparedness, is essential given evolving security considerations. Our aim is to help ensure that various regions of the world are not caught unprepared if smallpox outbreak becomes an unfortunate reality.

Regarding international markets, I'd like to discuss a regulatory development in Europe. At the end of July, the EMA's Committee of Medicinal Products for Human Use, or CHMP, commenced a referral procedure for tecovirimat. The CHMP raised questions about the product's efficacy in treating mpox following a review of the data from the recent mpox clinical trials, including PALM007 and STOMP.

As part of the referral procedure, the CHMP has provided a detailed set of questions largely focused on the mpox trials and will evaluate all non-clinical and clinical data to determine if the product maintains a positive benefit-risk ratio for its approved indication.

Our priority right now is to provide thorough, science-based responses to the agency's questions and fully support the referral procedure.

As a reminder, tecovirimat was developed as a smallpox treatment with the goal of reducing mortality, and is backed by a robust and comprehensive data package. It has been studied extensively and has demonstrated a strong safety profile in humans. In pre-clinical trials, tecovirimat significantly reduced mortality and viral load across four pivotal studies in non-human primates and two in rabbits, each of which, it is important to note, was designed to replicate smallpox in humans.

It remains the only antiviral approved in the EU for smallpox treatment, and it stands out for its strong safety profile. Safety has been demonstrated in about 10,000 tecovirimat recipients across more than 20 clinical trials, including normal, healthy volunteers and patients with mpox in open-label or double-blinded, placebo-controlled studies. Should there ever be a smallpox outbreak, we believe tecovirimat would serve as a critical countermeasure for mass distribution given its strong safety profile.

Turning to our late-stage pipeline, we continue to advance the TPOXX post-exposure prophylaxis program for smallpox, or PEP. Collaboration with the CDC, in consultation with the FDA, remains active as the CDC continues to move toward completing the required analysis of the samples collected to support the study's immunogenicity objective. The FDA has remained closely engaged with us on this program, offering real-time guidance that we believe has strengthened our regulatory plan. The CDC continues to expect to complete their work during the fourth quarter. As such, we're targeting an FDA submission for the PEP indication in 2026.

Also in our pipeline, our pediatric program continues to move forward in partnership with the Biomedical Advanced Research and Development Authority, or BARDA, within the U.S. Department of Health and Human Services under the Administration of Strategic Preparedness and Response, or ASPR. This initiative is designed to address an important unmet need—providing a treatment option for children too small for the current oral formulation of TPOXX. Clinical trial material has been manufactured, and we remain on track to submit an IND in the second half of this year, with the trial targeted to begin thereafter.

As we look toward the second half of the year, our focus remains clear: sustaining a strong financial foundation and executing our strategic priorities with discipline. We continue to concentrate on the core areas that we have consistently delivered results and positioned us for durable success.

First, continuing our partnership with the U.S. Government. Second, advancing regulatory approvals of TPOXX in new indications. Third, cultivating strategic partnerships to expand global access to TPOXX. Fourth, leveraging our capabilities to move into complementary therapeutic areas.

In closing, we believe SIGA remains well equipped to continue its progress over time, building on its long history of public and private successes with a focused strategy, financial discipline, differentiated TPOXX franchise, and a proven track record. We're moving forward with purpose, staying true to our role in supporting global preparedness and driving meaningful shareholder returns.

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

Daniel Luckshire

Thanks, Diem.

As noted earlier in the call, SIGA's product sales for the three months ended June 30, 2025, are $79 million. Product sales for the quarter comprised $53 million of oral TPOXX sales and $26 million of IV TPOXX sales to the U.S. Government under the 19C BARDA contract. For the six months ended June 30, 2025, product sales are $85 million.

In addition to product sales, the Company has research and development revenues of approximately $2 million and $3 million for the three and six months ended June 30, 2025, respectively.

As a supplemental note, there are $26 million of remaining outstanding orders as of June 30. This amount reflects the $26 million IV TPOXX order received in the first quarter of this year under the 19C contract, which is targeted for delivery in 2026.

Pre-tax operating income for the quarter, which excludes interest income and taxes, is approximately $46 million. For the six months ended June 30, 2025, pre-tax operating income is approximately $43 million.

Net income for the quarter as well as the six months ended June 30, 2025, is approximately $35 million. In turn, fully-diluted income per share for the three and six months ended June 30, 2025 is $0.49 per share.

The Company continues to maintain a strong balance sheet. At June 30, 2025, the Company had a cash balance of approximately $182 million and no debt.

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 up for questions.

Operator

Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. Should you have a question, please press star, followed by the one on your telephone keypad. You will hear a prompt that your hand has been raised. Should you wish to cancel your request, please press star, followed by the two. If you're using a speakerphone, 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. Please go ahead.

Jyoti Prakash

Hi, good evening, and thank you for taking my questions. First of all, congratulations on the strong sales performance in the quarter. My first question is related to the $13 million BARDA funding for the pediatric program. How do you plan to deploy these funds? If you can, comment on the likely trial design and the data required for a possible approval?

Diem Nguyen

Yes, Jyoti. Nice to hear from you, and thanks so much for this question. This is a really important program for SIGA because we believe it is important to be able to develop a formulation to protect a very vulnerable population. BARDA has been very supportive of this program throughout the development process, and this additional funding reemphasizes the importance of tecovirimat to the U.S. Government. This investment will fund development activities up to a regulatory filing.

As it relates to the study design, by the way of background, in 2023, we initiated and concluded a Phase I study that evaluated an oral suspension formulation prototype in healthy adults for the development of a pediatric powder for oral suspension formulation. That study looked at a range of factors with a primary goal to understand how the drug, in this formulation, behaves in the body after a single dose compared to a TPOXX capsule.

We're now preparing for the follow-up trial which will evaluate a refined formulation designed to deliver tecovirimat dose appropriate for pediatric use. It will be a single-dose crossover study that also examines how different meal types affect absorption. This ensures that children receive a safe and effective dose that mirrors adult exposure levels.

Jyoti Prakash

Thank you for the explanation. My second question relates to your international growth efforts. You mentioned the CHMP requesting additional data from the mpox trial, and if you look at the recent quarters, you've had strong order demand, and you have delivered significant orders. I just want to understand this new data request, how does this impact your plans for international growth and expansion?

Daniel Luckshire

Hi, this is Dan. I'll take that question. Maybe as a starting point, the background is that we took over international promotion and marketing from Meridian last summer. Over the past year, we have been spending considerable time strengthening and building relationships with current and potential customers around the globe, and all this effort is really centered on expanding our international business and ensuring countries are prepared in case of a smallpox outbreak.

As you're aware, there's a lot of preparation and groundwork that's part of the international effort. Given the current geopolitical instability and the stockpile strategies for these individual countries, we do believe that we are building an international business that has significant potential. In terms of timing of future sales activity, we expect international orders to continue to be lumpy. With that context, I would highlight that we have sold $135 million of oral TPOXX to 30 countries since 2020, and we do believe that that shows the depth and the scope of the international opportunity.

Jyoti Prakash

Thanks for the clarification, Dan. Moving on to the U.S. market, you talked briefly about the RFP process in your ongoing conversations, but do you have any further clarity on the timelines for the RFP? Secondly, assuming the RFP is received in the second half of the year, what would be the typical lead time between order receipt and delivery?

Daniel Luckshire

This is Dan. I'll also respond to that question. I think there's two components in there and it's mostly focused on some of the mechanics. We had some prepared remarks on this, but as you can imagine, it's difficult for us to speculate on the exact timing and form of the U.S. Government RFP. What we can say is that we do believe that we have seen recent confirmation of the U.S. Government's commitment to biodefense this quarter, with the combination of the deliveries of TPOXX, which have been substantial, and the two commitments for development funding that we talked about, both in our prepared remarks as well as our press release. That development funding adds up to $27 million, which is a meaningful number.

With that backdrop, our focus does remain on fostering the strong partnership that we've had for a very long time, really over a decade. This partnership does—this ongoing partnership plays a vital role in supporting what we believe is national security and public health efforts, and we really think that's valuable. It's worth a lot. Overall, we do believe we're well positioned to engage with the U.S. Government on RFP when they are ready.

In terms of process, I think there's a part of your question about just timing on process. I would say that there are many variables, but in short, maybe I could just use the 2018 process—these are long-dated contracts. That was the last contract we did with the United States Government that lasted until recently in terms of orders. In that process in 2018, there's an RFP that was put out. Now granted, in this situation, the RFP could be both open competition or it could be sole source justification. It could be a variety of different forms, but in 2018, there's an RFP that was put out, and then after the RFP, you'd enter a negotiation process. In 2018, from start to finish, in terms of negotiation, took six months.

Having said that, the timeframe could vary in either direction given the Administration change. We would be as efficient as possible. We've gone through many procurement processes, and we will be very efficient, and we are prepared, and we're not aware of any impediments to the negotiation process going much faster than six months if the U.S. Government desires it.

Jyoti Prakash

Thank you, Dan. I have one final question, and this is related to the preclinical monoclonal antibody program which was licensed in late 2024. Just wanting to understand what's the current status of the program, and what are your plans for clinical development?

Diem Nguyen

Thank you, Jyoti. This is Diem. I'll take that. First and foremost, I would just begin by saying that we remain quite enthusiastic about the opportunity to expand our pipeline with this portfolio of preclinical fully human monoclonal antibodies which can be used as a potential treatment for a broad range of orthopoxviruses, both as a therapeutic as well as a prophylactic measure. These monoclonals have demonstrated promise in preclinical models, and we are looking to potentially execute on programs to determine the benefits of using this as a standalone treatment or in combination with TPOXX. We're currently working through a process to determine the best path forward for these assets from a development and manufacturing perspective, and we'll keep you apprised with our plans as we progress.

Jyoti Prakash

Thank you. No further questions from my side.

Operator

Thank you. Once again, should you have a question, please press star, followed by the one on your telephone keypad.

There are no further questions at this time. I will now hand the call back to Diem Nguyen for any closing remarks.

Diem Nguyen

Thank you.

I'd like to first by thanking everyone here for making the time to join today's call and for your ongoing interest in SIGA. We look forward to speaking to you again in our third quarter call. Have a good evening.

Operator

This concludes today's call. Thank you for participating. You may now disconnect.