



**SIGA Technologies, Inc.**

**Business Update Call**

**May 7, 2024**

## CORPORATE PARTICIPANTS

**Diem Nguyen**, *Chief Executive Officer*

**Daniel Luckshire**, *Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

**Soo Romanoff**, *Edison Group*

**Brian Adams**, *CarterTerry*

## 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 statement 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, 2023, and the subsequent reports on Form 10-Q and Form 8-K.

### Diem Nguyen

Good afternoon, everyone and thank you for joining today's call and review of our business results for the first quarter of 2024.

I am joined by Dan Luckshire, our Chief Financial Officer, and we are pleased to have this opportunity to provide an update on our Company. After the update, we'll be happy to answer your questions.

Overall, SIGA delivered a strong quarter as our team continues to execute on a high level. Our performance reflects the strength of this team, the value of our TPOXX franchise, and the steps we're taking to advance our strategy.

In the first quarter, SIGA reported product revenues of \$24 million and a pre-tax operating income of \$11 million, both up over the comparable quarter of 2023. These revenues were generated from the delivery of oral TPOXX in connection with orders placed by the U.S. and certain International Governments. We are

working diligently to sustain this positive momentum throughout the remainder of the year. We believe 2024 is lining up to be another year of strong financial performance. A central reason for our confidence is our expectation that we will receive another oral TPOXX order in the near term under the current BARDA contract.

In addition to generating strong durable financial results, we are focused on positioning SIGA for long-term success through our strategic choices, executing on key operating initiatives, and exercising disciplined capital management. We are doing this through four initiatives to drive shareholder value. Number one, continuing our partnership with the U.S. government; two, advancing regulatory approvals of TPOXX in new indications and formulation; three, cultivating the strategic partnerships to expand global access to TPOXX; and four, leveraging our capabilities to move into complementary therapeutic areas.

This quarter, we made progress on several fronts. A key development took place in April when we amended our agreement with Meridian Medical Technologies for the international promotion of TPOXX, effective June 1, 2024. This move not only enables us to control the marketing and promotion of oral TPOXX outside the U.S., but it also enhances our ability to connect and serve our customers more effectively and seamlessly.

Additionally, we strengthened our leadership by appointing a new Vice President of International Markets who brings a wealth of pharma experience, which includes procurement to International Governments and sales and marketing to private industry leaders. We believe this more focused approach will grow and strengthen our international presence, which is crucial amid rising orthopoxvirus threat.

In Japan, our partner, Japan Biotechno Pharma, announced in April that they've filed a new drug application for TPOXX for the treatment of smallpox, mpox, cowpox and complications due to the vaccinia virus. If approved, we anticipate that TPOXX will be placed on the National Stockpile ready for deployment in event of an mpox outbreak. Consistent with standard practices, we expect to receive an update on the filing early in the third quarter.

We also continue to advance our efforts to expand TPOXX approvals in new indications and formulations, particularly with our PEP and mpox programs. First on PEP, as stated last quarter, we believe that TPOXX has the potential to benefit smallpox patients in prophylactic situations. This use is consistent with how the U.S. Department of Defense is authorized to deploy TPOXX today under the Expanded Access Protocol for its personnel. In short, we've successfully completed the FDA's requirements to obtain extended safety data in humans with treatment for 28 days. This trial confirmed TPOXX's existing strong safety profile.

We also completed a JYNNEOS-TPOXX immunogenicity trial to evaluate TPOXX when administered concomitantly with JYNNEOS. The FDA requested we run this trial because in an event of an outbreak, TPOXX treatment would likely be used in combination with smallpox vaccine to reduce the morbidity and mortality in the population without sacrificing patient safety. We are continuing to work with the CDC on the collection and analysis of the data from this trial, in consultation with FDA and expect greater visibility on the path forward in the coming weeks. At the same time, we're working on our supplemental NDA submission and target to submit it early next year.

Shifting gears to the ongoing mpox trials. The sponsor of these trials continued to enroll patients and collect data. In Africa, as of April, the NIAID PALM trial being conducted in the Democratic Republic of Congo had enrolled 522 patients, a large increase from the 425 patients noted on our last call. In the NIAID STOMP trial, as of April, there were 350 patients, which is also a substantial increase from the 267 patients noted in our last call.

Before proceeding, I'd like to acknowledge the concerning increase in mpox cases, particularly in the DRC, where the government recently declared an epidemic. The CDC reports that the DRC is experiencing its

largest surge of mpox cases ever recorded, with over 19,000 suspected cases and more than 900 deaths from January 2023 until about a week ago. Furthermore, the predominant strain in the DRC, also known as Clade I, causes more severe illness and death compared to the strain during the 2022 global outbreak.

Since 2019, SIGA has been supporting investigators and health agencies in the DRC to reduce the devastating impacts of mpox disease. We have already donated over 500 courses of TPOXX capsules and its matching placebo for a randomized clinical trial use in the DRC. We continue to monitor the situation actively to provide assistance when possible.

Beyond Africa, orthopoxviruses continue to permeate around the world. We are committed to working closely with mpox trial sponsors to complete their trials and analyses as quickly as possible to achieve the best possible outcome for mpox patients. As a reminder, in Europe and the UK, TPOXX, known as Tecovirimat SIGA, has a broad label and has been approved to treat smallpox, mpox, cowpox and complications following vaccination against smallpox. In the U.S. and Canada, TPOXX has been approved for the treatment of smallpox with ongoing trials for mpox and PEP, as discussed earlier.

With regard to the important U.S. market, as we look forward to fulfilling any remaining oral TPOXX orders under our current contracts to supply TPOXX to the U.S. Strategic National Stockpile, we are ready to work in close collaboration with the U.S. government on the next contract for SNS stockpiling.

Our partnership with the U.S. government spans over a decade, with contracts totaling about \$1 billion and reinforces our collective commitment and responsibility to health security. We are confident in our ability to provide superior value to the U.S. government and collaborate with them to achieve the best outcome for public health security, SIGA shareholders and patients. Our aim is to secure a long-term contract with annual purchases that reflect TPOXX value today and in the future with a potentially expanded label.

As a reminder, smallpox remains a Category A bioterrorism agent according to the CDC. A recent report issued by the National Academies of Sciences, Engineering, and Medicine titled Future State of Smallpox Medical Countermeasures, concluded that this action is needed to enhance U.S. readiness for smallpox and related diseases, as well as to improve diagnostics, vaccines and therapeutics that can be used in response to an outbreak.

The COVID-19 pandemic and the 2022 mpox outbreak highlighted opportunities for strengthening the U.S. public health care systems in response to future health threats. We are prepared to do our part as we believe effective therapies and vaccines are essential to combat an outbreak, whether naturally occurring, accidental or intentional.

Overall, our Company is strong and profitable, supported by a robust strategy, a disciplined approach to capital management, a valuable TPOXX franchise, and a resilient team with proven operational capabilities. We are executing our strategy with urgency while maintaining our focus on advancing public health. Combined, we believe this will enhance shareholder value over time.

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

**Daniel Luckshire**

Thanks, Diem.

As noted earlier in the call, SIGA's financial results for the three months ended March 31, 2024, substantially surpassed the financial results for the comparable quarter in 2023.

Product sales for the three months ended March 31, 2024, were approximately \$24 million in comparison to approximately \$6 million of product sales in the comparable 2023 time period. Product sales in the first quarter of 2024 were related to deliveries of oral TPOXX to a diverse mix of customers. Approximately \$16 million of oral TPOXX was delivered to the U.S. government, including \$15 million of deliveries to the U.S. Strategic National Stockpile and a \$1 million delivery to the U.S. Department of Defense, and approximately \$8 million of oral TPOXX was delivered to eight international customers, with seven of those customers located in Europe.

Pre-tax operating income, which excludes interest income and taxes, was approximately \$11 million for the first quarter of 2024. In comparison, there was a pre-tax operating loss of approximately \$2 million in the comparable period in 2023.

Net income for the first quarter of 2024 was approximately \$13 million versus a net loss of approximately \$1 million in the first quarter of 2023. In turn, fully diluted income per share for the first quarter of 2024 was \$0.14 versus a comparable fully diluted loss per share of \$0.01 in the first quarter of 2023.

At March 31, 2024, the Company continued to maintain a strong balance sheet with a cash balance of approximately \$144 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 mentioned by Diem 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 financial performance based on our expectation that we will receive another oral TPOXX order in the near-term under the current BARDA contract.

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

**Diem Nguyen**

Thanks, Dan.

With that, I'll end where I began. SIGA delivered a strong quarter as our team continued to execute at high levels. We remain focused on positioning SIGA for the long-term success for the benefit of our patients, partners, and shareholders.

Now I would like to 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 star followed by the one on your telephone keypad. You will hear a three tone prompt acknowledging your request. Questions will be taken in the order received. Should you wish to cancel your request, 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. Once again, that is star and one to ask a question.

Your first question comes from the line of Soo Romanoff from Edison Group. Please go ahead.

**Soo Romanoff**

Hi. Great quarter. Congratulations, everybody. It's nice to see a lot of things lining up as we were hoping. My first question was on the BARDA contract. I believe we had \$112 million for oral TPOXX and \$26 million for IV TPOXX, and it seems like we got a big chunk of that this time. We had some—maybe some manufacturing challenges before, but it seems like we've worked that out. Do we expect the balance of that to come in, in 2024, I assume? Or is there going to be any spillover into 2025?

**Daniel Luckshire**

Right. This is Dan. Thanks for the question. I guess there's two parts of your question. In terms of, you did mention the vendor packaging issues in '23. We have been working with the packaging vendor in terms of smoothing out that process and really getting back into a rhythm that we had prior to 2023. As background, this is a long-standing vendor, and historically, it was relatively smooth. We did have a hiccup towards the end of last year. We have been working with them to smooth it out and really be prepared as much as possible for what we anticipate to be an upcoming order.

With that, in terms of talking about specificity about timing of deliveries, in terms of 2024 versus 2025, it's probably a little premature to really comment on specificity on whether all the order will be delivered in 2024. Having said that, and the reason we say that, is it's not just the packaging vendor, but also the other considerations are, is when the order comes in and when and where the government wants deliveries. There is a series of variables. As we get further in the year, we'll have a little more clarity on the details there. I would like to highlight, though, that as we noted in our prepared remarks, we do anticipate an order, and we do believe that 2024 is lining up to be a strong year financially based on our expectations. We do think it will be substantial, but in terms of specificity, we'll have to get back to you.

**Soo Romanoff**

Okay. Thank you. That's really helpful. Then also on the Meridian contract, I know that there is some amended terms for the international distribution. Could you help me understand how that works now? I think previously, the Meridian fee was around 20% of sales, and the revised fee figure for the new contracts internationally might be a little different.

**Diem Nguyen**

Soo, let me take that question. First, let me start by highlighting that the amendment is strategically important in that it enhances our ability to connect and serve our customers more effectively and seamlessly. Regarding the terms of the amendment, effective June 1, 2024, there will be a high single-digit fee percentage for international sales in the European economic area, Australia, Japan, Switzerland and the United Kingdom. If I were to summarize, I would say, first, we were able to reduce the scope of the international sales that will be subject to a fee; and second, reduce the fee percentage for those sales that are subject to a fee. International sales other than those in the European economic area, Australia, Japan and Switzerland and the United Kingdom, will not have a fee. We're quite enthusiastic about our ability to play a more direct role in international sales and confident of our ability.

**Soo Romanoff**

That's great news. That's amazing. Thank you for answering my questions. Congratulations again on a great quarter.

**Operator**

Thank you. Once again that is star and one to ask a question.

Your next question comes from the line of Brian Adams from Carter, Terry.

**Brian Adams**

Yes. Hi. Again, I just want to reiterate, great quarter for you guys. A couple of quick questions just for a clarification. When you speak of the upcoming fulfillment of the BARDA contract, I'm assuming that's the fourth and final tranche of the original agreement. Is that correct?

**Daniel Luckshire**

Yes. You're correct in that for oral TPOXX, there's four options for \$113 million each, and this would be the fourth and final option within the current contract.

**Brian Adams**

Okay. Then it begs the question, are you in early talks to do a part B or a secondary run of the TPOXX for the Defense Department? Is that a discussion that would be happening now and then also would potentially be on track for some time in late Q4 of '25 or first part of '26 based upon the cadence of how the orders have been filled in the time passed.

**Diem Nguyen**

Thanks, Brian. Although we haven't yet received notice from the Administration of Strategic Preparedness and Response about its plans for issuing another RFP for the U.S. National Stockpile, we are preparing for it some time this year. Our aim is to secure a long-term contract with annual purchases that reflect the value of TPOXX provided today as well as the future based on the potentially expanded label, which will include mpox as well as PEP.

**Brian Adams**

Okay. Then just a secondary question. With the STOMP trial, which has been going on for a good 18 months or so, not to put words in your mouth, do you feel somewhat frustrated of the results and how long this has taken as far as getting results? Any color or comment from the FDA on this?

**Diem Nguyen**

From the STOMP trial perspective, as noted, it is sponsored by the NIAID and has enrolled over 350 patients as of April. There has been a substantial increase from what we noted from our last call. April 2024 was the highest recruitment month to date for the STOMP trial, which is currently enrolling about roughly 50 patients per month. We're not at all frustrated with the pace given the fact that we're seeing high recruitment. As it relates to current FDA guidance on target enrollment, the study will be fully enrolled in 2025, and we would caution that there's a lot of variables that will impact timing until recruitment is complete. However, we are working closely with our partners to file with FDA as soon as we can.

**Brian Adams**

Okay. Great. Thank you for the question and your time. Thank you. Great quarter. Appreciate it.

**Diem Nguyen**

Thank you.

**Operator**

Thank you. Ms. Diem Nguyen, there are no further questions at this time. Please proceed.

**Diem Nguyen**

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

**Operator**

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