



**SIGA Technologies, Inc.**

**Business Update Call**

**March 12, 2024**

## CORPORATE PARTICIPANTS

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

**Daniel J. Luckshire**, *Executive Vice President and Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

**Soo Romanoff**, *Edison Group*

**Lance Kimbrough**, *Ivy Creek Capital*

## 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 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.

I will now hand the call over to Diem Nguyen, CEO of SIGA. Please go ahead.

### Diem Nguyen

Good afternoon, everyone, and thank you for joining today's call and review of our business results for the fourth quarter and full-year of 2023.

I am joined by Dan Luckshire, our Chief Financial Officer; and we're pleased to have this opportunity to provide an update to our shareholders. After the update, we'll be happy to answer any other questions.

I'd like to begin by recognizing the work and contributions of Phil Gomez, who served as SIGA's CEO for seven years. Phil was instrumental in transforming our Company into a more commercial organization, with sales in over 25 countries and securing key regulatory approvals for our TPOXX franchise. On behalf of our team, I want to thank Phil for his many contributions to making SIGA the strong company it is today.

On a personal note, I'm excited to join SIGA and take on the role of CEO. Having spent nearly three decades focused on addressing unmet needs in health care, I look forward to building on SIGA's success and driving greater growth for the benefit of our patients, customers and shareholders. I have a deep-seated passion for scientific advancement and innovation, as well as an extensive experience leading successful multi-billion-dollar commercial organizations. I'm extremely excited to leverage this experience to help fulfill SIGA's potential and have our essential therapies available worldwide.

Although this is only my sixth week with the Company, I'm pleased to share my belief in SIGA's bright future. This belief has been grounded for the following: first, SIGA has strong business fundamentals. It is a highly profitable company with a management team that has deep expertise in commercial activities, antiviral R&D, and government relations. The Company has built and maintains a fully integrated U.S.-based operational supply chain. This is a distinguishing asset for our customers.

Second, TPOXX is a foundational product franchise that has a track record of securing multi-year government contracts, which have totaled over \$1 billion in the past 10 years. Again, this is a point of distinction and speaks to the significant value of TPOXX.

Third, SIGA has achieved best-in-class financial performance. Our average annual pre-tax operating income over the past four years has been \$75 million. These results have been achieved while maintaining a strong balance sheet.

Fourth, SIGA has attractive growth opportunities. Let me just mention a few. In the near term, SIGA has the potential to expand the indications of TPOXX to include post-exposure prophylaxis, which we like to call PEP, and mpox. I'll provide an update on these programs a little later in these remarks.

Also in the near-term, SIGA has the opportunity to expand geographically and work with governments across the world to fully embrace stockpiling and preparedness for a full range of orthopoxvirus risks. We want to ensure governments have a modernized view of the risks and the tools for protection against orthopoxviruses. Thinking more broadly, SIGA has strong antiviral and government procurement capabilities. We believe these capabilities are best-in-class that we can leverage to move into complementary therapeutic areas with similar points of patient care.

Importantly, all of this has reinforced TPOXX's leadership among infectious disease countermeasures. SIGA's expertise and experience in commercial execution, R&D innovation and government contracting enables us to support the highest level of public and individual safety.

As a result of these four critical factors, I believe SIGA is well positioned for further innovation, strong business performance, and attractive value creation for our shareholders.

Now turning to our financial results. I am very pleased to report that we finished the year strong. Full year 2023 product revenues of \$131 million are the highest amount achieved over the past five years. This reflects a 51% increase over 2022. Approximately \$116 million of the full-year product revenues were achieved in the fourth quarter, coming from a diversity of sources, including the U.S. Strategic National Stockpile, or the SNS, the U.S. Department of Defense, and five international governments.

Pre-tax operating income was approximately \$84 million in 2023, a 96% increase over 2022. This is a testament to the strength of the SIGA team, the value of our franchise, and the resilience of our Company. Dan will provide more details on these results shortly.

Additionally, in 2023, we spent \$43 million on capital management through a combination of a special cash dividend and share buybacks. I'm pleased to announce that our Board of Directors has declared a special dividend of \$0.60 per share to be paid in April. This represents a 33% increase over the special dividend

we paid in June of 2023. This demonstrates the financial strength of our Company and the confidence the Board and the Management team have in our future.

Our proven track record, coupled with the potential of a new long-term contract with the SNS provides both a compelling and attractive backdrop for our Company in both the short and longer term. Looking forward, we plan on continuing to invest to grow our business, while maintaining a balanced and disciplined capital allocation approach, with the goal of delivering strong long-term revenues and earnings growth, and creating value for our shareholders.

Now, I would like to talk about our PEP and mpox programs. With regard to PEP, I will start by recapping what was reported on the last investor call. Based on the studies and trials that have been conducted, we believe TPOXX benefits patients in a prophylactic situation. The FDA has not asked for any additional studies to prove the efficacy of TPOXX for PEP, but has asked for extended safety data in humans for treatment for 28 days. We have completed this requirement and the data is consistent with prior safety studies.

It is important to emphasize the clinical trial results do not show any drug-related serious adverse events, consistent with TPOXX's existing strong safety profile. In addition to the safety trial, we have completed a JYNNEOS-TPOXX immunogenicity trial solely to evaluate if TPOXX has an impact on vaccine immune response because, in the event of an outbreak, TPOXX treatment would likely to be used in combination with a smallpox vaccine.

In the preliminary analysis of the data from the immunogenicity trial, consistent with what we expected, the results did not show a meaningful difference between immunogenicity of those who receive the JYNNEOS vaccine while on placebo compared to those who received the JYNNEOS vaccine while on TPOXX. However, as mentioned previously, the results indicated that the number of volunteers who had measurable immune response to the JYNNEOS vaccine in both the placebo and TPOXX groups was lower than expected. Given these results, the data was deemed difficult to assess for the "non-inferior" statistical determination, which was necessary for the primary endpoint as originally planned in the study.

On the last investor call, we also reported that a subset of the JYNNEOS + TPOXX samples from the immunogenicity trial were sent to our colleagues at the CDC, who performed their validated PRNT analysis on them. These samples showed the expected immune responses. As such, we are now working on getting the entire set of the samples re-analyzed, given the challenges associated with the prior analysis conducted by our CRO vendor.

We believe these preliminary CDC analyses provide a potential path forward despite the unexpected nature of the prior results. As such, in parallel, we are working toward a supplemental NDA submission within the next 12 months. We are grateful to our colleagues at the CDC for this collaboration and efficient path forward. We believe this is the best course of action in terms of getting timely data from the immunogenicity trial, and the FDA agrees as they have been briefed on our plans and have not voiced any objections.

As a final comment on the PEP program, I want to emphasize that the immunogenicity 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. Rather, the relevance of the immunogenicity study is that in the case of an orthopoxvirus epidemic, be it mpox or smallpox, use of TPOXX with the vaccine for PEP will be important to reduce the morbidity and mortality of the population without sacrificing patient safety.

Now I would like to shift gears and provide a quick update on the current mpox trials involving TPOXX, which includes four randomized controlled trials, as well as multiple observational studies. These studies continue to enroll patients and collect data. To provide some specific data points:

In Africa, as of February, the NIAID PALM trial being conducted in the DRC has enrolled approximately 425 patients, a large increase from the 314 patients noted in our last call. In the NIAID STOMP trial, as of February, there were 267 patients, which is also a substantial increase from the 157 patients noted in our last call.

These increases in patient numbers demonstrate that the case counts continue to accumulate, especially in Africa. Importantly, they also provide a glimpse - some would say a warning - into the overall global health risk posed by orthopoxviruses. As such, we are working closely with the 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 to achieve the best possible outcome for mpox patients from a public health perspective. I would like to remind you that TPOXX is approved for smallpox, mpox, cowpox and vaccinia complications in Europe and in the U.K.

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

**Daniel J. Luckshire**

Thanks, Diem.

As noted earlier in the call, SIGA's strong performance was represented in 2023. Product sales for the 12 months ended December 31, 2023, were \$131 million, which is the highest amount achieved over the past five years, and reflects a 51% increase over 2022.

\$116 million of the full-year product sales were achieved in the fourth quarter, coming from a diversity of sources, including the U.S. Strategic National Stockpile, the U.S. Department of Defense, and five international governments. Fourth quarter product sales include SNS product sales of \$98 million through the delivery of oral TPOXX, \$6 million of oral TPOXX sales to the U.S. Department of Defense, and \$12 million of international sales in oral TPOXX, most of which relate to orders under the HERA contract announced in October of 2023.

I would like to add that the process of product deliveries under existing orders, which started in the fourth quarter of 2023, continued in the first two months of 2024, with approximately \$15 million of deliveries of oral TPOXX to the SNS and approximately \$7 million of international deliveries of oral TPOXX.

Pre-tax operating income, which excludes interest income and taxes, was approximately \$84 million for 2023. This represents an increase of 96% over the corresponding 2022 amount. I would like to note that average pre-tax operating income for the past four years, the time period of 2020 to 2023, is \$75 million. We believe this average, and the 2023 financial results, highlight the robust earnings power of SIGA.

Continuing the strong performance, net income for 2023 was \$68 million, an increase of approximately 100% from the corresponding amount in 2022. In turn, fully-diluted income per share for 2023 is \$0.95 versus \$0.46 in 2022.

At December 31, 2023, the Company maintained a strong balance sheet, with a cash balance of approximately \$150 million and no debt. In 2023, SIGA spent approximately \$43 million of capital management, with a special cash dividend of approximately \$32 million and share repurchases of approximately \$11 million. Earlier today, the Company declared a special cash dividend of \$0.60 per share, payable on April 11 for shareholders of record after close of business on March 26.

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

**Diem Nguyen**

Thank you, Dan.

Before I conclude our prepared remarks, I'd like to offer one more insight to my role as CEO. I am committed to creating value for our shareholders by doing what I believe is in the best long-term interest of our Company, partners, and patients. I am bringing a fresh perspective, with a sense of urgency, to our strategic planning, operational processes, development efforts, and capital allocation, just to name a few. You'll be hearing more from me in the coming months as our plans evolve and we leverage the progress and momentum from 2023 into 2024.

In summary, our Company is at an exciting and important launch moment as we strategically invest in our research and development programs, expand geographically by broadening our partnerships with governments around the world, leverage our antiviral experience and expertise to pursue attractive opportunities in other therapeutic areas with similar points of patient care, and continue initiatives that directly benefit our shareholders.

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

**Operator**

Thank you.

(Operator Instructions)

Your first question is from Soo Romanoff from Edison Group. Please ask your question.

**Soo Romanoff**

Great. Thank you for taking my questions, and congratulations on the quarter. It's nice to see the healthy distribution. My first question was on oral TPOXX delivery. It looks like we'll mark the last deliveries under the 2018 contract with BARDA for oral TPOXX. Have we had any other further discussions with the U.S. government on possible extensions to the contract or new long-term rolling SNS contracts?

**Diem Nguyen**

Thank you, Soo, for the question. We want to share that we have maintained a continued as well as healthy dialogue with the U.S. government. At this time, we're targeting an RFP for the SNS from the Administration of Strategic Preparedness and Response this year. Specifically, we're not in a position to pinpoint the exact timing, but we do know that we're prepared to engage in any conversation and address any needs that they may have. Thank you.

**Soo Romanoff**

My second question was really on HERA. That was a really big milestone for SIGA. Have we seen any incremental opportunities developed in the last few months? We saw that nice double-digit million procurement deal that was already signed. What kind of other sales potentials can we assume looking ahead?

**Diem Nguyen**

At this point, as you have all been aware, we have sold to more than 25 countries. There are multiple countries in Europe and beyond who have ordered in the past who are indicating interest in ordering more TPOXX, often in larger quantity than the prior order. These conversations tend to be productive, yet iterative. We will share once we are able to. I will note that we've had \$21 million in international sales in 2023, and we are looking to strengthen these sales in the years ahead.

**Soo Romanoff**

Great. Thank you so much.

**Operator**

(Operator Instructions)

Your next question is from George (Inaudible), a Private Investor. Please ask your question.

**George**

Hi, yes. I'm not sure if you covered this earlier in the call, but do you—does SIGA still have an option coming up for later this year, the final option exercise for TPOXX for the U.S. government?

**Daniel J. Luckshire**

Yes. This is Dan. You're correct in that the existing contract does have a remaining option for \$113 million for oral TPOXX, as well as an IV TPOXX option for \$26 million. I would note that (multiple speakers). I'm sorry, go ahead.

**George**

That's for the '24 fiscal year?

**Daniel J. Luckshire**

That's what we're targeting to get exercised this year.

**George**

Okay. Thank you.

**Operator**

Thank you. Your next question is from Lance Kimbrough from Ivy Creek Capital. Please ask your question.

**Lance Kimbrough**

Congratulations on the great 2023 results. My question was related to—in the last quarter call, you had highlighted that there was some manufacturing bottlenecks that were holding up deliveries. It looks like or it sounds like you've worked through those. It was also mentioned that the reorder cycle for 2024 would be approximately \$128 million. Do you feel like manufacturing capacity now is such that you can meet that target if it's fulfilled?

**Daniel J. Luckshire**

Sure. This is Dan. I'll start off and Diem can jump in if she wants. Yes, we did navigate the slow pace of the supply chain towards the end of the year. We are still working on getting that to a more normalized way. I'm not going to say that it's back to where it was a couple of years ago, but we did manage to get deliveries within the fourth quarter for the most part. Going forward, it will be a continuing focus. Timing is important in terms of when the order comes in, and in terms of when deliveries are made. Provided that we get a timely order from the U.S. government, we'll be working toward making at least a substantial portion of the deliveries this year.

**Diem Nguyen**

Lance, I would just add that given my experiences running large, commercialized organizations, I recognize the importance of a strong manufacturing capability. Within the weeks that I joined, I started to take a deep dive on the manufacturing partnerships, and how we can be more effective in communication. You will see that we will be working toward successful delivery of products in the future.

**Lance Kimbrough**

Great. All right, well, congratulations again on the great results.

**Diem Nguyen**

Thank you, Lance.

**Operator**

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

**Diem Nguyen**

Well, thank you, Jenny. I just want to pause and say thank you for everyone for their time today and their continued interest in SIGA. As I mentioned in my remarks earlier, SIGA is in an exciting and important launch moment. We look forward to providing you an update with our progress next quarter. Thank you to everyone. Have a great day.

**Operator**

Thank you. Ladies and gentlemen, the conference has now ended. Thank you all for joining. You may all disconnect.