# Management Presentation

September 2017

# Forward Looking Statements

The statements made in this presentation may include forward-looking statements regarding the treatment of orthopoxvirus infections, the development and attributes of SIGA Technologies, Inc. ("SIGA") products, and the future operations, opportunities or financial performance of SIGA. Although we believe that the expectations contained in this presentation are reasonable, these forward-looking statements are only estimations based upon the information available to SIGA as of the date of this presentation. Except as required by law, we expressly disclaim any responsibility to publicly update or revise our forward-looking statements, whether as a result of new information, future events or otherwise. Thus, the forward-looking statements herein involve known and unknown risks and uncertainties and other important factors such that actual future operations, opportunities or financial performance may differ materially from these forward-looking statements.

Undue reliance should not be placed on forward looking statements, which speak only as of the date hereof. All forward-looking statements contained herein are qualified in their entirety by the foregoing cautionary statements.

For a more detailed discussion of our risks, see the Risk Factors section in SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC and our other filings with the SEC, including our most recent Quarterly Report, all of which are available on our website, www.siga.com.



SIGA Human BioArmor

# SIGA Value Proposition

| | |
|---|---|
| **Growing Public-Private Markets** | • Biodefense is a $9.5B global market with an 8.3% CAGR[1]<br>• Attractive market expansion opportunities |
| **Critical Need** | • Bioterrorism is a recognized, urgent threat that could kill millions in a single outbreak<br>• Smallpox is one of the deadliest threats with a historical 30% fatality rate<br>• Vaccines alone cannot address a smallpox outbreak |
| **Favorable Policy and Regulatory Environment** | • Unique market dynamics, regulations and policies support multiple potential revenue streams for the TPOXX product line |
| **Proven Track Record** | • Experienced management and strategic collaborations enhance prospects for success<br>• Over $500 million in contract awards from the U.S. Government<br>• Highly externalized cost structure minimizes fixed costs and provides scalability |
| **Multiple Catalysts for Growth** | • Significant opportunities for value creation around SIGA's antiviral therapy for smallpox |

[1] Grand View Research, Published October 2016.

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# Lead Program TPOXX Current and Potential Revenue

| Revenue Streams | Description / Status |
|---|---|
| Oral Drug (U.S. Gov) | • Procurement and Development Contract of $472 million for 2 million courses of drug for 18-64 yr. olds; potential expansion for coverage of all ages<br>• Replenishment of product deliveries that started in 2013<br>• Potential future expanded indication for post-exposure prophylaxis based on additional studies |
| IV drug (U.S. Gov) | • Currently in Phase 1 development; granted fast track status<br>• Enrollment in Phase 1a study completed<br>• Development contract from U.S. Government |
| Priority Review Voucher (PRV) | • 21st Century Cures Act established PRV program for Medical Countermeasures<br>• Potential eligibility for PRV upon NDA approval for TPOXX (anticipated in 2018) |
| International | • Focused business development program in numerous countries<br>• FDA approval of TPOXX is a key milestone to support procurement planning |
| Private Sector | • Hospitals, large corporations, and specialty retail stockpiles for emergency use |

**Substantial NOLs providing tax benefits for current BARDA contract and future contracts**

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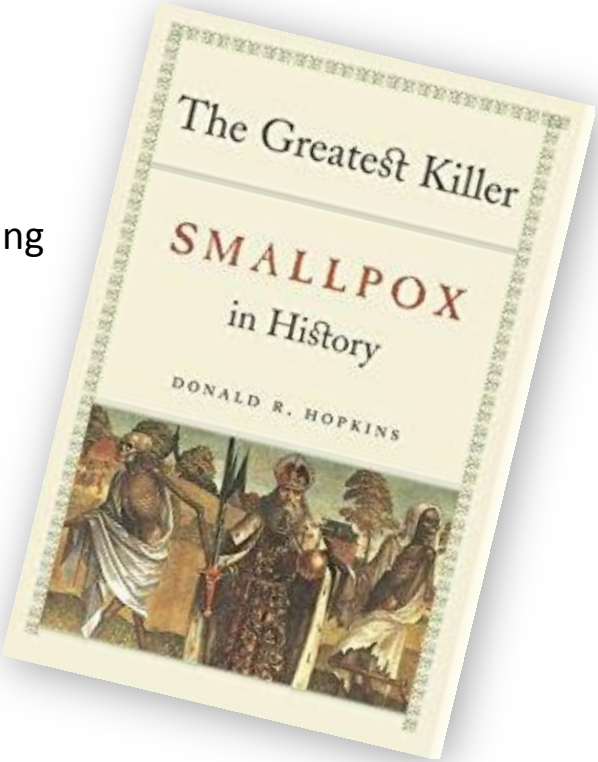
# Smallpox: A Deadly Killer

- Smallpox has a **potential 30% fatality rate** and was responsible for approximately **300 million deaths** worldwide in the 20th century
- Smallpox is a **highly contagious** virus
  - Spreads person to person
  - Can be transmitted through speaking, breathing, or touching
  - Can be transmitted by direct contact with infected fluids and contaminated objects
  - It is estimated that each person infected with smallpox would infect 5-7 other people if not vaccinated/treated
- Successful eradication resulted from coordinated global vaccination campaigns
- Current smallpox vaccine and other vaccinia-based vaccines may cause serious adverse reactions, especially in individuals who are very young or very old, or immunocompromised (e.g., those with eczema or atopic dermatitis)

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# Compassionate Use in Treatment of Vaccine Complications

## 2007

- *28-month old child*[1-3]
  Diagnosed with eczema vaccinatum after contact with his father, an active U.S. military service member who had recently received smallpox vaccination

1

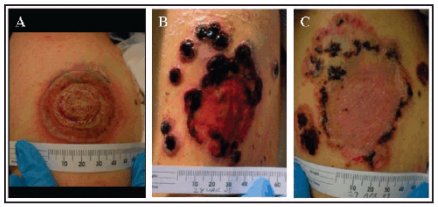
FIGURE. Abdomen and chest of a boy aged 28 months with a rash of umbilicated lesions caused by eczema vaccinatum — United States, 2007

Photo/John Maroinak

## 2009

- *20-year old active U.S. military service member*[4,5]
  Presented with progressive vaccinia after receiving smallpox vaccination

4.5




- *35-year old female*[6]
  Developed a vaccinia infection after exposure to a recombinant vaccinia-based rabies vaccine

## 2011

- *25-year old female*
  Developed a vaccinia infection after changing a bandage covering a smallpox vaccination site for her boyfriend, a U.S. military contractor

## 2015

- *Active U.S. military male service member*
  Developed vaccine complications due to a concomitant undiagnosed cancer

[1]Science. 2007;316:1418-1419. [2] CDC MMWR. 2007;56:478-481. [3]Vora S et a. Clin Infect Dis. 2008;46: [4]CDC MMWR. 2009;58:532-536. [5]J Infect Dis.2012;206:1372-1385. [6] CDC MMWR. 2009;58:1204-1207.

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# The Challenges of Smallpox Today

**Today's population is not immune from smallpox[1]**

**1980**

Smallpox eradicated; routine vaccinations and boosters ceased

**Smallpox vaccine cannot treat all individuals[2]**

**20%**

Percent of the population contraindicated for vaccination

**Treatment with vaccine must be immediate[3]**

**FOUR DAYS**

Treatment window when patients receiving vaccine benefit after infection

**Immediate treatment nearly impossible[1]**

**14 DAYS**

Period when infected individuals typically do not show symptoms

[1]CDC Fact Sheet: Smallpox .Available at https://www.cdc.gov/smallpox/symptoms/index.html. [2]Studies Cite Smallpox Vaccine Tradeoff. *The Washington Post*. May 8, 2002. [3] Henderson DA et al. Clin Infect Dis. 2003;36:622-629.

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# The Threat of Smallpox Tomorrow

**"Somebody would reconstruct, say, a smallpox virus and have that spread, and that would not only kill millions, it could potentially kill billions."**

*Bill Gates on bioterrorism, Jan 28, 2017, PBS*

**"…the next epidemic could originate on the computer screen of a terrorist intent on using genetic engineering to create a synthetic version of the smallpox virus …"**

*Bill Gates, Feb 18, 2017, Business Insider Op-Ed*

Watch: Bill Gates on Bioterrorism, PBS

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# Significant Government Investment in Preparedness

- U.S. government initiatives to support preparedness:
  - Project Bioshield (2004)
  - Formation of the Biomedical Advanced Research and Development Authority - **BARDA** (2006)
    - Supports development and procurement of countermeasures for bioterrorism attacks, including drugs considered priorities for national health security
    - Smallpox identified as a major threat
  - Pandemic and All-Hazards Preparedness Act Reauthorization (2014)
- Between 2001 and 2014, the U.S. government spent nearly **$79 BILLION** on civil biodefense funding[1]

[1]Sell TK and Watson M. Biosec Bioterror. 2013;11:196-216. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3778993/.



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# Attributes of an Ideal Smallpox Therapeutic

## Easy to…

**STORE**

Small molecule with long shelf life

**TRANSPORT**

Stable without the need for refrigeration

**ADMINISTER**

Oral and IV formulations

**TPOXX is one of the first new molecular entity drugs delivered to the Strategic National Stockpile under Project BioShield**

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# The Impact of an Antiviral on a Smallpox Attack

# Smallpox is Highly Contagious and Deadly

It is estimated that, in the absence of a vaccine or antiviral therapy, each person infected with smallpox will infect 5-7 other people, and that approximately 30% of infected individuals will die

**Even with vaccination, published models have shown the use of an antiviral drug during an outbreak could significantly reduce fatalities, confirming the importance of maintaining significant stockpiles**

Original infection

Newly infected individual

Fatalities

Sources: Centers for Disease Control, World Health Organization, Center for Infectious Disease Research and Policy, National Center for Biotechnology Information, Journal of Biosecurity and Bioterrorism, and presented to HHS, CDC, BARDA, FBI, Homeland Security, DoD, the White House and overseas.

[1] Published in the Journal of Biosecurity and Bioterrorism, and presented to HHS, CDC, BARDA, FBI, Homeland Security, DoD, the White House and overseas.

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# SIGA is Uniquely Positioned to Address the Threat of Smallpox

# SIGA: Advancing Health Security

**MISSION**

A commercial-stage specialty pharma company focused on developing solutions to infectious disease and biothreats

**VALUABLE THERAPEUTIC PORTFOLIO**

*TPOXX® (tecovirimat)*

Oral capsule smallpox antiviral

- Targeting NDA filing in late 2017
- >$500 million of contract awards from U.S. Government

IV formulation smallpox antiviral

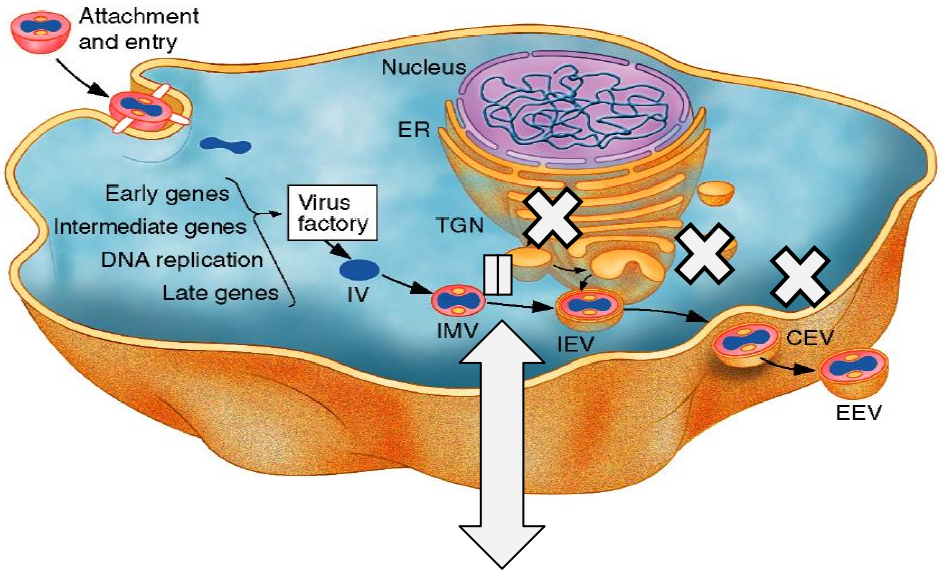
- Enrollment in Phase 1a study completed
- Development contract from U.S. Government

Dengue Virus Antiviral

Preclinical: efficacy shown in animal models

# TPOXX Mechanism of Action

- Smallpox spreads by developing a secondary envelope
- This allows the virus to leave the cell and enter the bloodstream
- TPOXX's mechanism of action **inhibits maturation, preventing release and spread of viral particles to other cells**




IMV: Intracellular Immature Virus
IEV: Intracellular Enveloped Virus
EEV: Extracellular Enveloped Virus

**TPOXX**

***Inhibits the viral envelope formation and spread of the virus***

[1] Byrd CM and Hruby DE. Viral proteinases – targets of opportunity. Drug Dev Res. 2006;67:501-510.

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# Therapeutic Portfolio: R&D and Sales

## R&D Status

| Program | Preclinical | Phase 1 | Phase 2 | Phase 3 | NDA Approval | Status | Next Steps |
|---|---|---|---|---|---|---|---|
| **TPOXX - Oral** | | | | | | Completed Enrollment of all Trials | NDA submission – Q4 2017 |
| **TPOXX – IV** | | | | | | Completed Phase I a | Phase 1 b Initiation |

## Procurement Status

| | Procurement Eligible | Stockpile maintenance | Status | Next Steps |
|---|---|---|---|---|
| **TPOXX - Oral** | $472 M[1] | | Delivering on Initial procurement | Stockpile maintenance and potential expansion |
| **TPOXX – IV** | | | R&D funded | Establish procurement contract |

[1] Procurement and Development Contract

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# Favorable Policy and Regulatory Environment Support Development and Future Demand for TPOXX

# Novel Development Path for TPOXX

## Development Path

- With smallpox declared eradicated in 1980, it is unethical to conduct efficacy testing in humans
- FDA 'animal rule' established to conduct efficacy studies in animals and safety studies in humans
- Required GLP efficacy studies completed in animals along with animal toxicology
- Sale of product for stockpiling prior to NDA approval

## TPOXX Status

- All Phase 3 clinical studies complete with no drug-related SAEs
- Dose concurrence agreement with FDA
- In vivo toxicology data and CMC data complete and being prepared for submission
- SIGA preparing NDA, with submission targeted for 4Q 2017
- Fast Track Designation and Orphan Drug Designation received, with anticipated NDA priority review

**Anticipated to be first novel small-molecule drug to be approved for biodefense**

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# Clinical Summary

| Summary of Subjects Treated | Number of Subjects |
|---|---|
| Received at least one dose of TPOXX | 359 |
| Received at least 14 days of treatments | 336 |
| Drug-related Serious Adverse Events | 0 |

| Clinical Trial Summary | | | |
|---|---|---|---|
| Total Trials | Phase 1 Trials *(Completed)* | Phase 2 Trials *(Completed)* | Pivotal Phase 3 Trial *(Completed)* |
| 11 | 9 | 1 | 1 |

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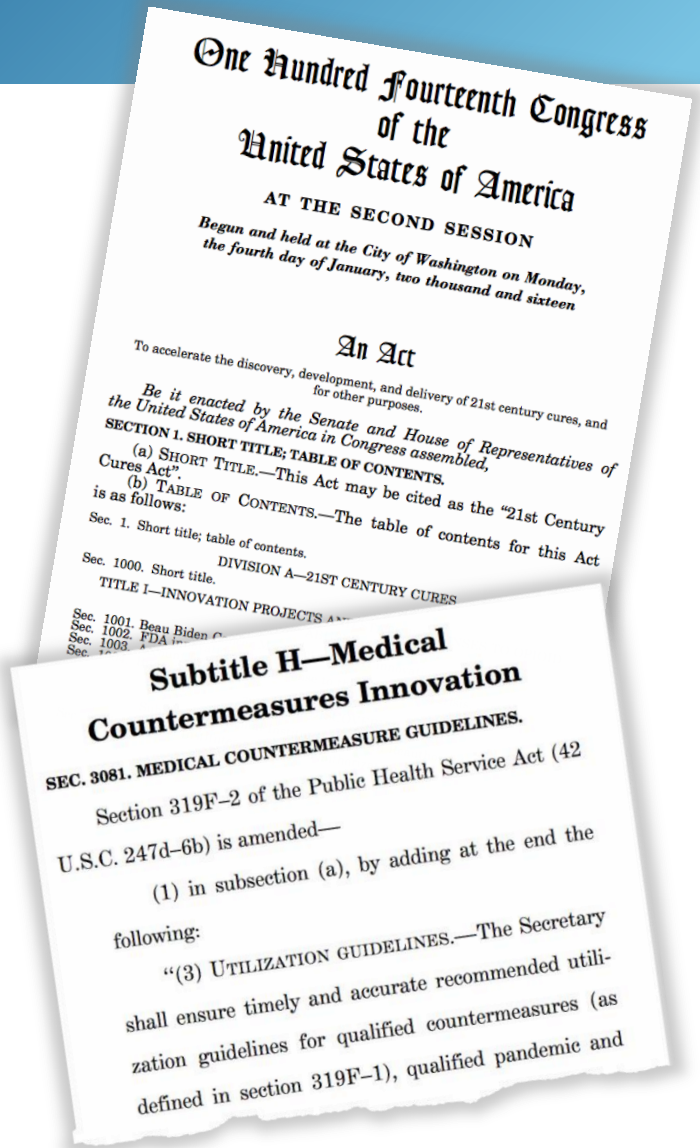
# Priority Review Voucher

- 21st Century Cures Act of 2016 created Priority Review Voucher (PRV) eligibility for Medical Countermeasures to material threats as determined by the U.S. Government
- Legislation provides the sponsor of a qualifying product with a PRV to receive priority review for a future drug of their choice, resulting in an accelerated review
- PRV may be sold commercially without restriction
- Smallpox is on the list of Material Threats, and TPOXX is a novel treatment for smallpox
- SIGA expects to apply for a PRV when the TPOXX NDA is filed; targeted for late 2017
- Upon NDA approval, FDA will determine eligibility and can award PRV. Targeted timing is 2H 2018



One Hundred Fourteenth Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen*

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS A

Sec. 1001. Beau Biden C

Sec. 1002. FDA

Sec. 1003.

Subtitle H—Medical Countermeasures Innovation

SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a), by adding at the end the following:

"(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and

[1]U.S. House of Representatives Amendment to the Senate Amendment to H.R.34.Subtitle H – Medical Countermeasures Innovation. Available at:http://docs.house.gov/billsthisweek/20161128/CPRT-114-HPRT-RU00-SAHR34.pdf.

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# Elements in Place For Manufacturing and Commercial Success

# U.S. Government Investment in Biodefense has Enabled SIGA to Build a Robust Capability for Drug Development and Commercialization

## End-to-end network of proven partners established

Discovery → Pre-clinical → Clinical → Regulatory → Supply Chain

- Over 20 partnered companies
- TPOXX developed from lead identification through commercial supply chain
- U.S. based supply chain for robust product supply to customers
- Experienced oversight of network by SIGA leadership
- Proven capabilities that can be scaled for future products

**Network design minimizes fixed costs and provides ability to scale to product development and procurement demands.**

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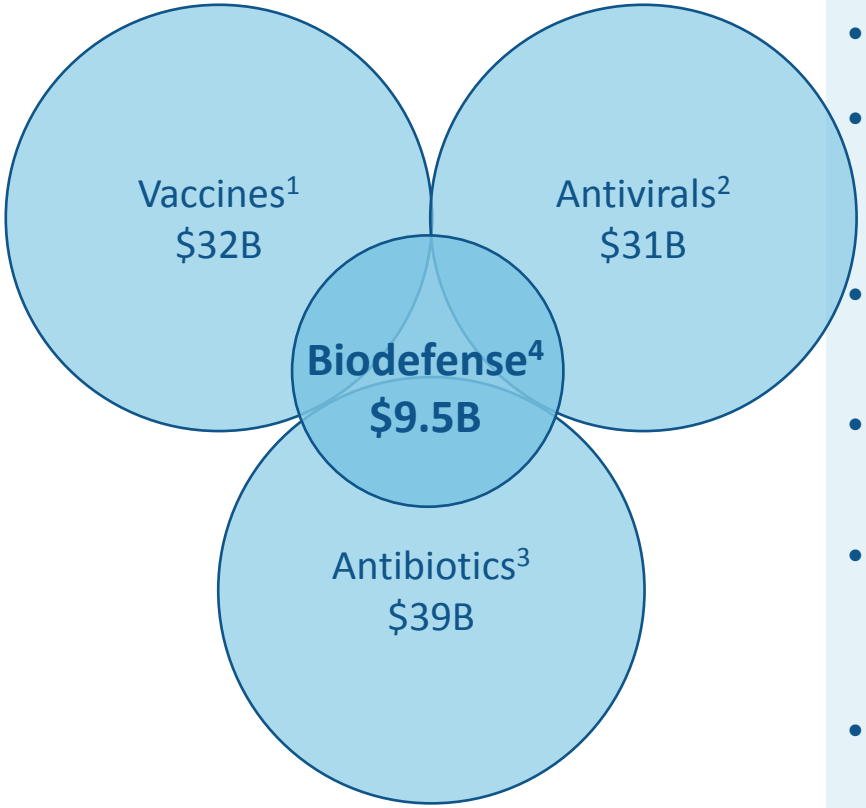
# Biodefense is an Attractive Specialty Market…




## MARKET INCENTIVES

- **R&D:** Government provides majority of R&D funding
- **Limited Buyers with Pre-Defined Volume:** Procurement contracts typically awarded multiple years prior to anticipated NDA, providing early cash flow
- **Priority Review Voucher:** Potential eligibility upon NDA approval, lucrative secondary market
- **Technology / Capability Platform Building:** Opportunity to build technology and expertise in product fields
- **Capital Investment:** In specialized products, shared capital investments have been made to build infrastructure for supply chain and/or R&D
- **High Barriers to Entry:** Complex government contracting requirements and long procurement cycles

**…that strategically overlaps with broader infectious disease markets.**

[1] Markets and Markets, 2016. [2] Mordor Intelligence, 2016. [3]Grand View Research, 2016.[4] Grand View Research, 2016.

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# Proven SIGA Leadership Team

**Phillip Gomez, Ph.D.** *CEO*
25+ years experience in Infectious Disease, Pharmaceuticals

**Daniel Luckshire,** *EVP, CFO*
20+ years experience in Specialty Business, Finance

**Dennis Hruby, Ph.D.,** *Chief Scientific Officer*
25+ years experience in Microbiology, Pharmaceuticals

**Robin Abrams,** *General Counsel and Chief Administrative Officer*
25+ years experience in Law, Government, Pharmaceuticals

**Tove Bolken,** *SVP, Operations*
15+ years experience in Microbiology, Pharmaceuticals

**Annie Frimm,** *VP, Regulatory, Clinical, & Quality*
25+ years experience in Pharmaceuticals

**Akhila Kosaraju, M.D.,** *VP, Global Business Development*
10+ years experience in Pharmaceuticals, Government

**Eric Rose, M.D.,** *Executive Chairman*
25+ years experience in Healthcare



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# Corporate Focus: 2017-2018

- Obtain FDA Approval for TPOXX
- Expand Sales of TPOXX Product Line
- Optimize Value of PRV Opportunity
- Leverage Proven Networked Capabilities
- Maximize Shareholder Returns

[1] Grand View Research, Published October 2016.

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