EDISON

SIGA Technologies

Initiation of coverage

Protection against a future pandemic

Pharma & biotech

SIGA Technologies is a commercial-stage company focusing on health security. Its lead program is oral TPOXX (tecovirimat), which was approved by the FDA in 2018 for the treatment of smallpox and is active against all orthopoxviruses. Importantly, in 2018 SIGA was awarded a 60-month contract (with options to extend to 2028) of up to $602m from the US Biomedical Advanced Research and Development Authority (BARDA), the majority of which was for the procurement of the oral version of TPOXX.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/19	26.7	(15.3)	(0.15)	0.0	N/A	N/A
12/20	125.0	82.0	0.82	0.0	8.0	N/A
12/21e	119.2	77.1	0.76	0.0	8.6	N/A
12/22e	124.5	81.4	0.81	0.0	8.1	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

Smallpox is a deadly threat to national security

Smallpox is a very serious, life-threatening disease caused by the variola virus. The literature suggests a death rate of up to 30% (compared to around 2% for COVID-19). Although eradicated, it could potentially be used as a bioweapon as the necessary components for its manufacture could potentially be purchased for approximately $100,000. According to CDC forecasts, over 50 million people could be infected in a smallpox outbreak (the TPOXX stockpile only has 1.7m courses).

Building on the label in the US

The bulk of the BARDA contract is related to the oral version of TPOXX in people with smallpox. The company is looking to expand its franchise with an IV version (NDA to be submitted shortly), a liquid formulation mainly for use in small children and a label expansion for TPOXX for use in post-exposure prophylaxis (PEP).

International expansion is a major opportunity

SIGA is partnered with Meridian Medical Technologies, a Pfizer subsidiary focused on health security, for international marketing of TPOXX. It recently announced two separate contracts with the Canadian government for the delivery of up to $47m worth of TPOXX and is working on other markets. Uptake from Europe, Japan, South Korea and Australia could potentially lead to a meaningful market opportunity.

Valuation: $968m or $12.61 per basic share

We value SIGA at $968m or $12.61 per basic share using a risk-adjusted net present value (NPV) model. Almost half of our valuation comes from the US base business, with the rest mainly coming from the PEP and international opportunities. The company reported $117.9m in net cash at the end of December and is profitable. SIGA has a $50m stock repurchase program in place and bought $28.5m of stock by the end of Q420.

5 March 2021

Price	**US$6.55**
Market cap	**US$502m**

Net cash ($m) at 31 December 2020	117.9
Shares in issue	76.7m
Free float	50.8%
Code	SIGA
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(0.6)	(6.2)	35.6
Rel (local)	2.1	(7.9)	12.6

52-week high/low	US$7.8	US$4.0

Business description

SIGA Technologies is a commercial-stage health security company focused on the treatment of smallpox and other orthopoxviruses. It has contracts with both the US and Canadian governments for TPOXX, its treatment for smallpox, and is looking to expand internationally.

Next events

IV TPOXX NDA submission	Q221
Canadian regulatory approval	Late 2021/ early 2022
EMA regulatory approval	Late 2021/ early 2022

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Edison profile page

SIGA Technologies is a research client of Edison Investment Research Limited

Investment summary

Company description: Preparing for the future

SIGA Technologies is a US-based commercial-stage pharmaceutical company that was founded in 1995 and went public in 1997. It is focused on treating smallpox, a very serious life-threatening disease caused by the variola virus that has a death rate of up to 30%. The US Centers for Disease Control and Prevention (CDC) considers it to be a Category A bioterrorism agent/disease as it can be easily disseminated and transmitted, has a high mortality rate and might cause public panic. SIGA's lead program is oral TPOXX, which was approved by the FDA in 2018 for the treatment of smallpox. In the same year, SIGA was awarded a re-supply contract by BARDA of up to $602m for the procurement of TPOXX into the Strategic National Stockpile (SNS) as well as additional research and development (there was an initial supply contract awarded to SIGA in 2011). The company is looking to expand its franchise with an IV version (NDA to be submitted in Q221), a liquid formulation mainly for use in small children and a label expansion for TPOXX for use in PEP.

Valuation: $968m or $12.61 per basic share

We are initiating coverage of SIGA at $968m or $12.61 per basic share using a risk-adjusted NPV model. This model factors in the current US and Canadian contracts and the additional IV and liquid formulations, the PEP label expansion and contracts with countries across the globe as COVID-19 has elucidated the dangers that a pandemic can cause a country in terms of both health and economic prospects. We view advancement of the PEP indication and contracts with major western economies to be key valuation inflection points for the company.

Financials: $117.9m in cash and cash flow positive

SIGA reported $117.9m in cash at the end of December and is profitable. For 2020, it reported $125.0m in revenues and net income of $56.3m. Its gross margin is typically over 80%, most of its R&D is reimbursed by the government and SG&A costs are relatively low as there is not a need for much of a dedicated salesforce (the commercial focus is mainly on government procurement). SIGA has a $50m stock repurchase program in place and bought $28.5m of stock to the end of Q420.

Sensitivities: Labyrinthian government procurement

Unlike a typical healthcare company, SIGA is heavily dependent on government procurement contracts, which have quite a few unknowns. The contracts are extended at the sole discretion of BARDA and are dependent on congressional appropriations, which can often be delayed due to political maneuvering in a divisive partisan environment. SIGA cannot get paid in the US market unless budget resolutions are passed in Congress. Additionally, the timing of TPOXX deliveries can also be unknown, which has created volatility and lumpiness in SIGA's revenues in the past. So, although we expect the company to have average annual product sales of over $100m per year for the next several years, some years can be significantly higher or lower. The prospects and timing for international expansion are unknown outside of Canada, which recently awarded two contracts to the company. There is also potential competition from brincidofovir, developed by Chimerix for the treatment of smallpox. There is a PDUFA date in April 2021 and brincidofovir could be included in the SNS. However, this likely will not affect SIGA's business with BARDA as the agency has often sought at least two sources. Additionally, the stockpile of 1.7m TPOXX courses is only enough to cover 0.5% of the population of the US, much less than what might be required in a widespread smallpox outbreak.

Company description: Expanding on TPOXX

SIGA's lead product, TPOXX, can already be considered successful with both an FDA approval and a $602m BARDA contract. However, this is just the beginning as the company is making efforts on several fronts to expand the TPOXX franchise, both in the US and internationally. Note, the company's R&D is mostly funded by the US government, so the net cost of development is exceptionally low. Additionally, as large human clinical studies are unethical (they would need to purposely infect people with smallpox), regulatory approval typically requires safety data in healthy subjects and efficacy data in two animal models. As the company is receiving procurement orders directly from governments for the purpose of stockpiling, regulatory approval is not necessary for landing such a contract. SIGA first received a contract from BARDA in 2011, which specified $508.4m in payments, seven years before FDA approval.

Exhibit 1: SIGA pipeline

Program	Region	Formulation	Indication	Status
TPOXX	US	Oral	Treatment of smallpox in those weighing >13kg	FDA approved 2018. $461m BARDA procurement contract (part of 2018 BARDA re-supply contract)
	Canada	Oral	Treatment of all human pathogenic orthopoxviruses (smallpox, monkeypox, cowpox, vaccinia) in those weighing >13kg	$33m contract with Public Health Agency of Canada and a $14m contract with the Canadian Department of National Defence. Regulatory approval expected in late 2021/early 2022
	US	IV	Treatment of smallpox in those too sick or unable to swallow capsules	$85m worth of procurement in 2018 BARDA contract. NDA filing targeted for Q221
	US	Liquid (powder for re-constitution)	Treatment of smallpox in people weighing <13kg (children)	Currently being formulated. Development fully funded by BARDA
	US	Oral	PEP	Up to $26m contract with the US Department of Defense signed in 2019 (expanded in 2020) for research in PEP. Two human studies planned, one to evaluate if there is interference with the Jynneos smallpox vaccine and an expanded safety study
	EU	Oral	Treatment of all human pathogenic orthopoxviruses (smallpox, monkeypox, cowpox, vaccinia) in those weighing >13kg	MAA submission July 2020
ST-357	All	Oral	Treatment of smallpox	Distinct mechanism of action from TPOXX and may be more broadly active. Target conserved in all chordopox viruses (orthopox, molluscum contagiosum, cervidpox). In preclinical testing

Source: SIGA Technologies

Smallpox

Smallpox is a serious infectious disease caused by the variola virus and humanity has had a long and tortured history with it. Smallpox is thought to have first appeared around the time of the first agricultural settlements, around 10,000 BCE, with the earliest evidence of the skin lesions typically seen in smallpox found on Egyptian mummies from 1570–1085 BCE. The first recorded epidemic came during the time of the Egyptian-Hittite war in 1350 BCE. Over the ages, smallpox killed millions. A large-scale epidemic in the Roman Empire thought to have been smallpox killed between 3.5 million to seven million people around 180 CE, including the Emperor Marcus Aurelius. Tens of millions of Native Americans are also thought to have died from smallpox after the European colonists brought it over and in purposeful use as a biological weapon through infected blankets during the French and Indian War.[1] In the 20th century alone, 300 million people have died from the infection.[2]

1 Barquet et al., Smallpox, the triumph over the most terrible of the ministers of death. *Annals of Internal Medicine*, 1997, vol. 127 (pg. 635-42)

2 Oldstone (2010) *Viruses, Plagues and History*, Revised and Updated Edition. Oxford University Press

It is usually spread through respiratory droplets that generally have a range of six feet but can be aerosolized and spread through a ventilation system, and only a few virions are thought to be necessary to cause infection. In 1970, 17 people in a German hospital on three separate floors developed smallpox despite none of the 17 having direct contact with the initial patient.[3] Smallpox has a long incubation period with no symptoms, but often turns into what many would consider a bad case of the flu. Following this, a rash develops that turns into sores and round, deeply embedded pustules. These pustules then begin to scab and only once the scabs have fallen off is the patient considered not to be contagious. The period where the patient is both symptomatic and contagious can last around three weeks (see Exhibit 2).

Exhibit 2: Stages of smallpox

Stage	Length	Symptoms	Contagious
Incubation period	7–19 days	No	No
Initial symptoms	2–4 days	High fever, body aches, vomiting	Sometimes
Early rash	Four days	Rash on the tongue and mouth that turns into sores that spread to all parts of the body in 24 hours	Yes, they are most contagious at this point
Pustular rash and scabs	10 days	Sores become pustules and then begin to scab	Yes
Scabs fall off	Six days	Scabs begin to fall off	Yes
Scabs no longer present	N/A	All scabs have fallen off	No

Source: CDC

Smallpox is generally one of the more transmissible of the serious infectious diseases and one of the most deadly. Someone exposed to an infected person has a 90% chance of contracting the disease themselves.[4] The reproductive number (R_0) of smallpox, which is the number of cases directly generated by one case in the population, is estimated to be between five and seven, while that of COVID-19 is estimated to be between 1.5 and 3.5 (see Exhibit 3). Even at this lower estimate, there have already been 102 million COVID-19 cases globally with 26 million cases in the US alone. Some CDC forecasts estimate that up to 54.5 million people could be infected with smallpox if it were used as a bioterrorist weapon.[5]

Exhibit 3: Transmissibility and fatality rates of various diseases

Disease	R_0	Case fatality rate (CFR)
Smallpox	**5–7**	**30%**
Diphtheria	6–7	7–8%
Ebola	1.5–2.5	51%
Influenza	0.9–2.1	<0.01%
Malaria	5–100	0.3–0.5%
Measles	12–18	4%
Mumps	4–7	0.01%
Pertussis	12–17	1–4%
Polio	5–7	10%
Rubella	6–7	0.20%
SARS	1–2.75	9%
MERS	1	35%
COVID-19	1.5–3.5	2%

Source: Fine, Herd Immunity: History, Theory, Practice. *Epidemiologic Reviews*, (1993) 15(2), 265–302. Kucharski et al., Case fatality rate for Ebola virus disease in west Africa. *The Lancet*, Volume 384, Issue 9950, P1260, October 4, 2014., Peeri et al., The SARS, MERS and novel coronavirus (COVID-19) epidemics, the newest and biggest global health threats: what lessons have we learned? *International Journal of Epidemiology*, Volume 49, Issue 3, June 2020, Pages 717–726. University of Michigan School of Public Health, CDC, WHO.

The danger of smallpox being used as a weapon is very real as the DNA sequence of the smallpox genome is in the public domain. A group of Canadian researchers were able to synthesize the horsepox virus, a relative of smallpox, in six months using about $100,000 worth of mail order

3 Weiss et al., Confronting Biological Weapons. *Clinical Infectious Diseases* 2004; 39:1668–73

4 Grosenbach et al., Oral Tecovirimat for the Treatment of Smallpox. *NEJM*. 2018;379:44-53.

5 Meltzer et al., Modeling Potential Responses to Smallpox as a Bioterrorist Weapon. *Emerging Infectious Diseases*. Vol. 7, No. 6, November-December 2001

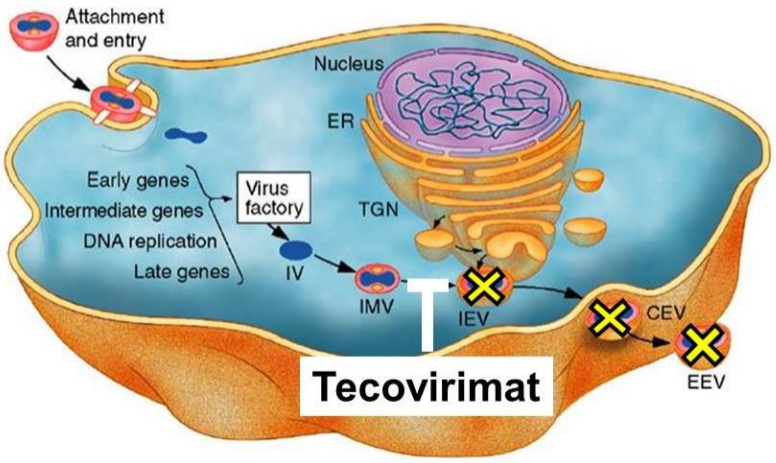
constituents. Separately, Tonix Pharmaceuticals announced that it was able to synthesize the horsepox virus. Additionally, methods have been published on how to engineer mousepox (another orthopoxvirus related to smallpox) into a highly virulent and vaccine-resistant form.[6] Additionally, the US and Russia maintain their smallpox stockpiles, with some highly virulent forms likely in the Russian one. Also, it has been reported that Russian researchers have travelled to other nations (such as Iran) to continue work on biological agents, potentially including smallpox.

While authorities used to require mandatory smallpox vaccinations for the general public, these generally ended in the 1970s, with the US no longer requiring a smallpox vaccination in 1972. Those vaccinated 50 years ago or more likely have almost no residual protection against smallpox transmission, but evidence does suggest there may be residual immunity against fatal complications of smallpox. In a study of outbreaks in Australia from the 1880s to early 1900s, the median duration of partial protection against severe smallpox was 31.7 years and 53.9 years against fatal complications of smallpox.[7]

TPOXX

TPOXX works by inhibiting viral spread to uninfected cells by specifically inhibiting the protein VP37 (also known as F13 and p37), which is involved in producing extracellular enveloped virions.[8] Extracellular enveloped virions are involved with spread of the virus between cells and systemic dissemination.[9] Importantly, this protein is highly conserved in all orthopoxviruses, which not only provides TPOXX with an advantage of broad applicability but makes animal testing with smallpox analogs (the only ethical method to test a smallpox treatment) more straightforward and more likely to be indicative of efficacy in humans.

Exhibit 4: TPOXX mechanism of action



Source: SIGA presentation at FDA AMDAC meeting

6 Jackson et al., Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox. *Journal of Virology* 2001 Feb;75(3):1205-10.

7 Nishiura et al., Estimation of the Duration of Vaccine-induced Residual Protection Against Severe and Fatal Smallpox Based on Secondary Vaccination Failure. *Infection*, 2006. 34(5), 241–246.

8 Chan-Tack et al., Assessing a drug for an eradicated human disease: US Food and Drug Administration review of tecovirimat for the treatment of smallpox. *Lancet Infectious Disease*. Volume 19, Issue 6, June 2019, Pages e221-e224

9 Bray et al., Looking Back at Smallpox. *Clinical Infectious Diseases*, Volume 38, Issue 6, 15 March 2004, Pages 882–889

Efficacy was determined in three pivotal studies in cynomolgus macaques infected with the monkeypox virus and an additional two pivotal studies in New Zealand white rabbits infected with rabbitpox. Mortality in these models is nearly universal, with a significantly shorter incubation period than that seen in humans. Human incubation periods can range from seven to 19 days (although are typically 12–14 days on average), while macaques develop skin lesions three to four days after infection, and the rabbits develop systemic viremia at around the same time (with fever consistently seen at day four). In animals treated with TPOXX at day four, when they became symptomatic, the survival rate was between 80% and 100%, with rates consistent between species (see Exhibit 5). As part of Study 3 in cynomolgus macaques, treatment at days five and six post-infection were also investigated, with survival rates for those treated five days after infection being 83% and survival for those treated six days after infection at 50%. This indicates that treatment once symptoms first start will be very important in helping people survive smallpox.

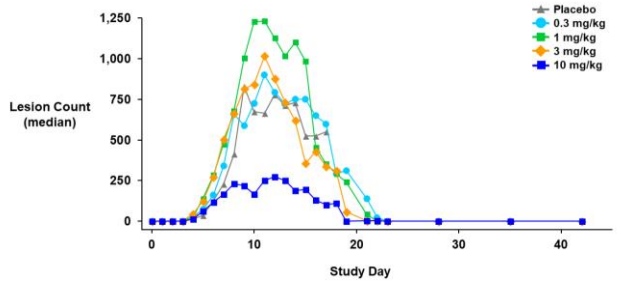
Exhibit 5: TPOXX animal study data – treatment at day four

Cynomolgus macaques	Survival TPOXX	Survival placebo	P value
Study 1	80%	0%	0.0038
Study 2	100%	0%	0.0002
Study 3	83%	0%	0.0151
New Zealand white rabbits			
Study 4	90%	0%	<0.0001
Study 5	88%	N/A	N/A

Source: TPOXX FDA label

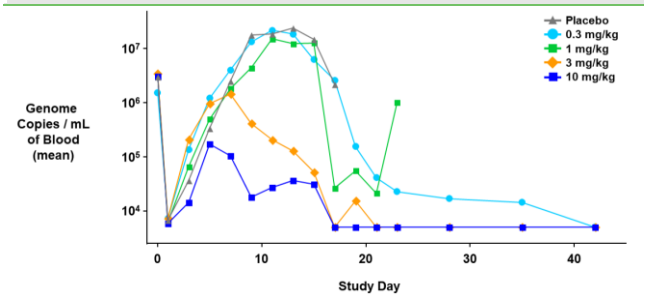
Additionally, besides the marked difference in survival, TPOXX also had dose-dependent effects on lesion counts and viral loads (see Exhibits 6 and 7).

Exhibit 6: Lesion counts in cynomolgus macaques



Source: SIGA presentation at FDA AMDAC meeting.
Note: 10mg/kg is the dark blue line.

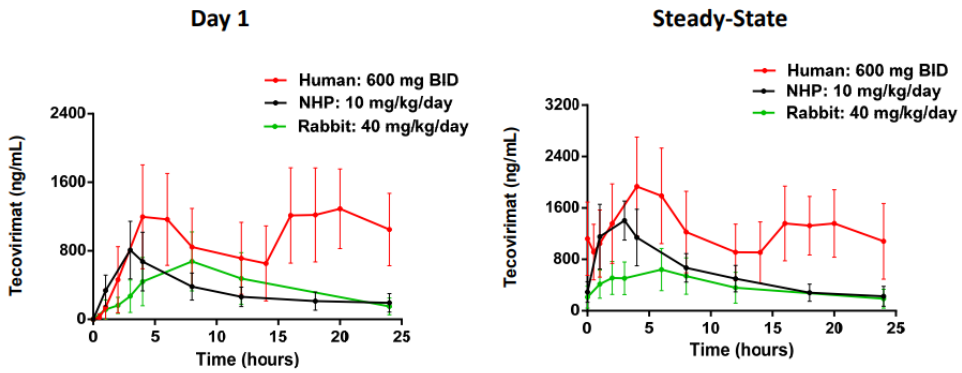
Exhibit 7: Viral load in cynomolgus macaques



Source: SIGA presentation at FDA AMDAC meeting.
Note: 10mg/kg is the dark blue line.

The effective doses in the studies were determined to be 10mg/kg in macaques and 40mg/kg in rabbits (although due to species-specific issues, the exposure level was higher in macaques). A dose of 600mg twice daily for 14 days was selected for human testing, with plasma concentrations higher than that seen in both macaques and rabbits (see Exhibit 8).

Exhibit 8: Plasma exposure comparison for humans, macaques (non-human primates [NHP])



Source: FDA presentation at FDA AMDAC meeting. Note: 10mg/kg is the dark blue line.

For human safety, SIGA ran a Phase III, randomized, placebo-controlled trial with 359 subjects given 600mg of TPOXX twice a day for 14 days and an additional 91 receiving placebo. TPOXX was demonstrated to be safe with only 2% discontinuing treatment in both placebo and TPOXX arms due to adverse events. In total, 37% of patients in the TPOXX arm reported an adverse event compared to 33% in placebo. There was a single serious adverse event in the TPOXX arm (a pulmonary embolism that resulted in death), but that was deemed unrelated to treatment.

US BARDA contracts and the SNS

TPOXX has been the subject of two separate BARDA procurement contracts; the first was signed in 2011 and expires in December 2024. Per the contract, BARDA agreed to buy 1.7m courses of TPOXX with an additional 300,000 provided at no charge. The contract specified $508.4m in payments, of which $459.8m was received for the delivery of TPOXX and $45.5m was received as reimbursement for development and support activities ($3.1m remains eligible to be received in the future as reimbursement for these activities).

In September 2018, SIGA received a re-supply contract for TPOXX for up to $602m, including $461m for procurement of up to 1,488,000 courses of oral TPOXX (~$310 per course) and $85m for the procurement of up to 212,000 courses (~$401 per course) of IV TPOXX. An additional $56m is allocated for development and support and is essentially used to help fund the company's R&D. Also, with a seven-year shelf life for oral TPOXX, we estimate that approximately one-seventh of the stockpile would need to be replaced on average every year (this varies depending on the timing of orders from BARDA). The base period for the contract is five years, with the potential to extend it to 10 years through the exercise of options (although this would not modify the contractual value or total dose quantities covered by the contract), which may mean this contract may be in effect until 2028. As of Q420, up to $424m of included potential payments from the 2018 BARDA contract are specified as unexercised options. Altogether, we assume there will be a continuing contractual relationship with the US government similar to its current form (with regards to pricing and volume) until 2034, when the final patents expire for TPOXX. However, we believe the contracts may extend beyond this as there are other barriers to entry for competitors beyond patents, such as the US government procurement system. Additionally, SIGA has a supply chain that is completely US-based, which we believe should be an advantage over the many generic companies that are reliant on international manufacturing.

The doses of TPOXX contracted by BARDA are in the SNS. The SNS also stockpiles three vaccines for smallpox: ACAM2000, Jynneos and Aventis Pasteur (although the Aventis Pasteur vaccine is considered investigational and would only be used if the other vaccines were depleted or not readily available). ACAM2000 is a live, replicating vaccine that carries the risk of considerable

side effects (black box warnings for myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, vaccinia, and Stevens-Johnson syndrome, among others) and is also contraindicated in immune-compromised individuals. Based on clinical studies measuring cutaneous response as a proxy for vaccination success, the vaccine has 84–96% effectiveness according to the FDA label. Additionally, the mode of administration is 15 jabs of a bifurcated needle.

Jynneos is a highly attenuated vaccine that does not replicate in human cells (making it much safer than ACAM2000) and vaccine effectiveness could not be judged by a cutaneous response as there was not one due to the attenuation. In a comparison of the neutralizing antibody response to ACAM2000, Jynneos was judged to be non-inferior although numerically it provided a greater number of neutralizing antibodies. One issue with the dosing is that there are two doses, four weeks apart, which limits the potential usefulness of the vaccine in a true smallpox emergency. Besides preventing infection by vaccinating before exposure, vaccines are thought to have efficacy if provided within three days of exposure (well within the incubation period when people are asymptomatic). If given four to seven days post-exposure there may still be some protection and people exposed to the disease may not get as sick. In an emergency, while vaccines may help protect a certain percentage of the population, as we have seen from COVID-19, timely distribution of vaccines in the US is not without challenges. Once there is an event, therapeutics such as TPOXX will be a very necessary component of the response to the crisis as they can be given at a later time post-exposure and appear to have far fewer side effects than vaccines.

There is also an additional therapeutic in the US stockpile, cidofovir, which is investigational and it is not known if a person with smallpox would benefit from it, according to the FDA. Chimerix is developing brincidofovir for the treatment of smallpox and has tested the therapy in New Zealand white rabbits, who were infected with rabbitpox, and BALB/C mice, who were infected with ectromelia virus. For the rabbits provided therapy three days post exposure, 100% survived, with 90% surviving if provided therapy four days post exposure (as in the TPOXX trials). In untreated rabbits, survival was 29% (compared to 0% in the TPOXX trials). Within the mice treated four days post-exposure, survival was 78% while those untreated had a survival rate of 13%. An NDA has been submitted for the product with a PDUFA date of 7 April 2021. If approved, we would expect a BARDA contract for brincidofovir, although we believe this would be in addition to TPOXX not as a replacement of it. As a reminder, the current TPOXX stockpile only covers approximately 0.5% of the US population and the number at risk is much higher (as mentioned, some CDC forecasts estimate that up to 54.5 million people could be infected with smallpox if it were used as a bioterrorist weapon).[10] Additionally, as brincidofovir had a higher survival rate within the placebo animals, the placebo-adjusted survival rate in the TPOXX trials appears to be higher, potentially indicating it may have superior data. We do not believe there are any other near-term potential competitors to TPOXX based on our research.

Label expansions

SIGA has a number of initiatives to expand on TPOXX in the US. The company is currently looking to expand its franchise with an IV version (NDA expected to be submitted in Q221) to treat those who are either too sick or unable to swallow oral TPOXX capsules. A total of $85m of the 2018 BARDA contract is allocated for the procurement of 212,000 doses of an IV version of TPOXX. Additionally, SIGA is working on a pediatric liquid formulation (technically a powder for reconstitution) for people weighing under 13kg. The reason for this is that TPOXX is given as three 200mg capsules twice daily for 14 days to those who weigh 40kg or more, two 200mg capsules for those who weigh between 25kg and 50kg and one 200mg capsule for those between 13kg and

10 Meltzer et al., Modeling Potential Responses to Smallpox as a Bioterrorist Weapon. *Emerging Infectious Diseases*. Vol. 7, No. 6, November-December 2001

25kg in weight. As there is no way to split a capsule in half, the mg/kg dosage would be too high for small children (and they would find it difficult to swallow a capsule). Timing is unclear for the liquid formulation, but development is underway.

The largest potential expansion of TPOXX would be in PEP. There is a one- to two-week gap in potential treatment of smallpox infection. Vaccines can protect against infection from before exposure to at most three to seven days after exposure. The current label for TPOXX assumes its use once symptoms have started after the incubation period (approximately 12–14 days after exposure on average). So there is a period of time when an exposed person would be unprotected by a vaccine and not likely to get TPOXX under the current labelling. The PEP program is looking to bridge that gap. Under PEP, TPOXX would be given to anyone who has been exposed to someone with smallpox given the high chance that person would become infected (as a reminder, someone exposed to an infected person has a 90% chance of contracting the disease themselves).[11] Colonel Peter Weina, chief of research at Walter Reed Military Medical Center, stated at the 1 May 2018 FDA advisory committee meeting that: 'The reality is that this [smallpox] is so highly infectious, post-exposure prophylaxis is going to be a knee-jerk reaction to anybody at any time if you've got anybody who's been diagnosed. So anybody who's within eyeball shot of somebody who's got a diagnosed case of smallpox is going to be getting this drug [TPOXX].'

According to the company, PEP treatment would be for a 28-day course of therapy (versus 14 days for the approved indication). If BARDA were to purchase an equivalent number of PEP courses compared to the current (post-infection treatment) contract, this opportunity could be double the size (due to double the treatment length and therefore double the number of capsules required). With regards to the development plan, the company has stated that two human studies are planned, one to evaluate if there is interference with the Jynneos smallpox vaccine and an expanded safety study. The studies may begin as early as Q321 (with timing somewhat dependent on the COVID-19 pandemic) with completion expected in 2022. Additionally, based on communications with the FDA, no additional animal studies will likely be needed for approval for the PEP indication. That said, it is uncertain exactly when TPOXX for PEP would be stockpiled (if at all) and it could occur before or after FDA approval. However, for the sake of conservatism and due to the lack of visibility, we currently forecast inclusion in the SNS in 2025. Note that SIGA has been awarded a research contract in 2019 (and expanded in 2020) for up to $26m with the US Department of Defense to support work on the PEP label expansion.

International contracts

SIGA is partnered with Meridian Medical Technologies, a Pfizer subsidiary focused on health security with a 50-year history of selling medical countermeasures globally, for the marketing of TPOXX outside the US. Other products marketed by Meridian include an antidote treatment for organophosphorus nerve agents such as Sarin and VX and a treatment for cyanide poisoning, among others. Exact terms of the Meridian agreement are undisclosed beyond that it will be a percentage of sales of oral TPOXX net of certain expenses, with the percentage increasing when exceeding a certain threshold.

In April 2020, the first contract outside of the US was signed with the Canadian Department of National Defence (CDND) for up to 15,325 courses of oral TPOXX over four years for a total of $14.3m. Note the per-course amount is $933, approximately triple what has been obtained from the US government. The reason for the lower price for the US government is that it helped fund the development of TPOXX and the large quantity of doses in the stockpile. The CDND made an initial purchase of 2,500 courses for $2.3m in Q220, with up to (subject to option exercise over the course of the contract) 12,825 courses to be ordered following Canadian regulatory approval (expected

11 Grosenbach et al., Oral Tecovirimat for the Treatment of Smallpox. *NEJM*. 2018;379:44-53.

late 2021/early 2022). With regards to the Canadian approval, the proposed indication would cover all human pathogenic orthopoxviruses such as smallpox, monkeypox (milder than smallpox but still deadly to around 10% of those who catch it, with a 2019 outbreak in Nigeria), cowpox and vaccinia.

In January 2021, SIGA received a second contract from a separate Canadian government agency. The Public Health Agency of Canada (PHAC) awarded a contract for up to $33m of oral TPOXX within five years (though total doses were unspecified). The contract specifies commitments for the purchase of $3.4m by 31 March 2021 and a cumulative purchase of $17.2m by 31 March 2023. The remainder will be purchased after that date with these purchases subject to option exercise by the PHAC.

We believe SIGA and Meridian will focus on key US allies, such as Europe, Australia, Japan and South Korea, and that SIGA will seek partnerships for other territories. The two companies may also be able to find additional clients in South America, Asia and Africa. The sales cycle for these international agreements will likely be long and it is unclear how many courses the different governments may purchase, but the COVID-19 pandemic will certainly have provided a concrete example of how disastrous a pandemic can be. We would expect additional contracts to be signed internationally in the coming years and we believe those contracts could be substantial in size (see Exhibit 9). It is important to note there is an undisclosed payment to Meridian for its international business development services, which will vary based on whether amounts exceed certain thresholds. We currently model this fee to be 20% of sales on average (the company has stated that it expects the margin on international agreements after manufacturing and Meridian fees to be between 65% and 80%). The company submitted an application with the EMA in July 2020 with a proposed indication similar to Canada's, covering all human pathogenic orthopoxviruses.

Exhibit 9: International market potential in select countries/regions

Country	Population (m)	Courses at midpoint of US and Canadian coverage levels	Potential contract size at midpoint of US and Canadian prices per dose ($m)
EU27	445.8	1,469,728	915
Germany	84.1	277,264	173
France	65.4	215,613	134
Italy	60.4	199,129	124
Spain	46.8	154,292	96
Ukraine	43.6	143,742	89
Poland	37.8	124,620	78
Romania	17.1	56,376	35
UK	68.2	224,844	140
Japan	125.6	414,082	258
South Korea	51.7	170,446	106
Australia	25.7	84,729	53

Source: Edison Investment Research

ST-357

SIGA is also developing ST-357, which is in a preclinical stage and has a distinct mechanism of action from TPOXX and may be more broadly active. The target is conserved in all chordopox viruses, including orthopox, molluscum contagiosum and cervidpox. Proof of concept has been demonstrated in three mouse models of orthopoxviruses. SIGA is pursuing support from the US government for further development of the compound.

Sensitivities

Unlike a typical healthcare company, SIGA is heavily dependent on government procurement contracts, which carry with them quite a few unknowns. The US contracts and included options are enacted and extended at the sole discretion of BARDA and are dependent on congressional appropriations, which can often be delayed due to political maneuvering in a divisive partisan

environment. SIGA simply cannot be paid in the US market unless budget resolutions are passed in Congress. Additionally, the timing of TPOXX deliveries can also be unknown, which has created volatility and lumpiness with SIGA's revenues in the past. So, while we expect SIGA to have average annual product sales of over $100m per year for the next several years, some years could be significantly higher or lower. The prospects for international expansion are pretty much an unknown outside of Canada, which recently awarded two contracts to SIGA. The prospects and timing for contracts from countries such as the EU, Japan, South Korea and Australia are unknown. There is also potential competition from brincidofovir, developed by Chimerix for the treatment of smallpox. There is a PDUFA date in April 2021 for brincidofovir and the treatment could be included in the SNS. However, this likely will not affect SIGA's business with BARDA as the agency has often sought at least two sources. Additionally, the current stockpile of 1.7m TPOXX courses is only enough to cover 0.5% of the population of the US, much less than what might be required in a widespread smallpox outbreak.

Valuation

We are initiating coverage of SIGA at $968m or $12.61 per basic share using a risk-adjusted NPV model. For both the US and Canadian oral TPOXX businesses, we use a 10% discount rate (our standard for commercialized products) and a 100% probability of success, as the contracts have been signed and there is no development risk. For the US base business for oral TPOXX, we assume there will be a contract with the US government similar to its current form (with regards to pricing and volume) until 2034, when the final patents expire for TPOXX. However, we believe the contracts may extend beyond this as there are other barriers to entry for competitors beyond patents, such as the US government procurement system. We take a similar approach to the Canadian contract although there is potential to greatly increase the stockpile there. The planned level of stockpile is only enough for approximately 0.1% of the population, which would likely prove inadequate in any smallpox pandemic scenario to protect anyone beyond a privileged few.

Our IV formulation estimate is based on the allocated amounts in the BARDA contract (reflecting $25.6m per order for bulk drug substance and final drug product), which we assume will occur on an annual basis, starting in 2023 (regulatory filing is expected in Q221). We assign a 90% probability of success, as it is about to be filed for approval, and use a 12.5% discount rate for this program, our standard for non-marketed products. For the pediatric formulation, as we have little detail on development timelines, we assume launch in 2025 with annual revenues of approximately 4% of those for oral TPOXX as that is the proportion of the population that is under 13kg in weight. We assign a 60% probability of success as it is still in formulation stages, although we do know the underlying active ingredient is safe and effective. We expect to increase this probability of success as this program progresses.

For the PEP program, we model double the number of treatment capsules and revenue potential given the 2x longer therapy duration, which is consistent with management's guidance for the opportunity. We expect launch in 2025 and assign a 40% probability of success. Although it is the same product as that for smallpox treatment and we expect it should work when administered before symptom onset, the program is still in development and there is also government procurement risk.

With regards to international markets outside Canada, we assume a 50% probability of success as there is very little visibility on what the level of uptake is going to be by the different governments. Otherwise, our $97m in peak annual sales assumes approximately 50% of the population of this group of countries will eventually be covered by a TPOXX stockpile. We also assume the stockpile size as a percentage of the population will be at the midpoint of the sizes of the US and Canadian stockpiles as well the price per dose. We expect to start seeing contracts in 2023, although this is

mainly for the sake of conservatism and there could be contracts coming in 2021 or 2022. Additionally, there is no reason why TPOXX stockpiles would need to be restricted to these countries as other countries face national security threats that may come from bioterror. That said, there is a wide range of potential outcomes for the international expansion of TPOXX, some of which we present in Exhibit 10.

Exhibit 10: Select potential international expansion scenarios

Penetration of potential national stockpiles	Doses as % of population	Cost per dose ($)	Peak annual sales ($m)	NPV (not risk adjusted, $m)
25%	0.1%	312	11	15
50%	0.1%	312	21	29
75%	0.1%	312	32	44
100%	0.1%	312	42	58
25%	0.1%	933	32	50
50%	0.1%	933	63	100
75%	0.1%	933	95	150
100%	0.1%	933	127	200
25%	0.3%	623	48	74
50%	**0.3%**	**623**	**97**	**148**
75%	0.3%	623	145	221
100%	0.3%	623	194	295
25%	0.5%	312	38	52
50%	0.5%	312	76	104
75%	0.5%	312	114	155
100%	0.5%	312	152	207
25%	0.5%	933	113	179
50%	0.5%	933	227	357
75%	0.5%	933	340	536
100%	0.5%	933	453	715

Source: Edison Investment Research

Based on the current stock price and our valuation model, it appears the current valuation is based on the existing contracts in the US and Canada but may not fully account for the upside coming from the additional formulations, PEP and international expansion, with the latter two providing the most potential upside. Also, in terms of normalized P/E multiples, the stock is trading at around 8x 2020 EPS, a discount to current P/E of 18x for Emergent BioSolutions (EBS), which is also in the health security space, and the P/E of approximately 28x for the S&P 500 Healthcare Index (the S&P500 as a whole trades at 40x). If the stock were to trade at our $12.61 valuation for the company, the P/E would be 15x, a slight discount with EBS but still at a meaningful discount to the larger market as a whole.

Exhibit 11: SIGA valuation

Product/program	Main indication	Status	Probability of success	Approval/launch/first contract year	Peak sales ($m)	rNPV ($m)
TPOXX (US base - oral)	Treatment of smallpox	On market	100%	2018	113	442
TPOXX Canada	Treatment of smallpox	On Market	100%	2020	9	35
TPOXX US IV and pediatric formulations	Treatment of smallpox	IV (to be filed 2021), pediatric (being formulated)	60–90%	2022–25	30	36
TPOXX US PEP	Post-Exposure Prophylaxis following exposure to smallpox	Development	40%	2025	225	264
TPOXX EU, Japan, Korea, Australia	Treatment of smallpox	Registration	50%	2023	97	74
Total						850
Net cash (Q420) ($m)						117.89
Total firm value ($m)						**968**
Total basic shares (m)						76.7
Value per basic share ($)						**$12.61**

Source: Edison Investment Research

Financials

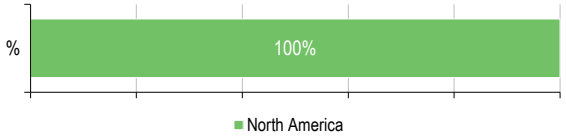
In 2020, SIGA reported $125.0m in revenues ($115.5m of which was product sales and services (including $2.3m from Canada) and the remaining $9.5m being reimbursed R&D) and net income of $56.3m. The gross margin for oral TPOXX was 87% and we expect that to expand as international sales, with a likely higher price point, become a greater portion of revenues. Our 2021 estimate for revenue is $119.2m, although we caution that actual results have shown high variability in prior years due to government procurement and budget schedules. There is also a new US administration in power and many political appointees have yet to be confirmed by the Senate. Orders and revenues could very well be back-end loaded to the second half of the year. Our revenue estimate also assumes no additional international contracts are signed, though the company has stated that it is in discussions with multiple governments. We expect reported net income to grow from $56.3m in 2020 to $58.6m in 2021. Given the generally low level of SG&A for the company and that R&D is substantially reimbursed by the US government, a high percentage of revenues from future growth should drop straight to the bottom line.

SIGA reported $117.9m in cash at the end of December and is profitable (although profitability for any specific period will depend on the timing of government orders and payments). SIGA also has a $50m stock-repurchase program in place and bought $28.5m of stock from March 2020 through the end of December. In addition to using cash for share repurchases, the company could use cash to fund growth and/or diversification initiatives.

Exhibit 12: Financial summary

$000s	2019	2020	2021e	2022e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	26,742	124,959	119,172	124,465
Cost of Sales	(1,783)	(14,797)	(15,696)	(15,956)
Gross Profit	24,959	110,162	103,476	108,508
Research & Development	(13,303)	(10,939)	(11,048)	(11,159)
General & Administrative	(13,978)	(14,722)	(15,311)	(15,924)
EBITDA	(27)	84,503	76,987	80,896
Operating Profit (before amort. and except.)	500	85,033	77,117	81,426
Intangible Amortisation	0	0	0	0
Other	2,822	532	0	0
Exceptionals	5,091	(8,507)	0	0
Operating Profit	5,591	76,525	77,117	81,426
Net Interest	(15,770)	(3,017)	0	0
Other	0	0	0	0
Profit Before Tax (norm)	(15,270)	82,016	77,117	81,426
Profit Before Tax (Reported)	(10,178)	73,509	77,117	81,426
Tax	2,937	(17,167)	(18,508)	(19,542)
Deferred tax	0	0	0	0
Profit After Tax (norm)	(12,332)	64,849	58,609	61,884
Profit After Tax (Reported)	(7,241)	56,342	58,609	61,884
Minority interest	0	0	0	0
Profit After Tax less Minority Interest (reported)	(7,241)	56,342	58,609	61,884
Average Number of Shares Outstanding (m)	81.0	79.3	76.7	76.7
EPS - normalised ($)	(0.15)	0.82	0.76	0.81
EPS - reported ($)	(0.09)	0.71	0.76	0.81
Dividend per share ($)	0.00	0.00	0.00	0.00
Gross Margin (%)	93.3	88.2	86.8	87.2
EBITDA Margin (%)	-0.1	67.6	64.6	65.0
Operating Margin (before GW and except.) (%)	1.9	68.0	64.7	65.4
BALANCE SHEET				
Fixed Assets	18,524	6,223	6,273	6,323
Intangible Assets	898	898	898	898
Tangible Assets	2,618	2,104	2,154	2,204
Other	15,008	3,221	3,221	3,221
Current Assets	180,042	143,608	204,048	267,762
Stocks	0	0	0	0
Debtors	4,168	3,340	3,340	3,340
Cash	160,987	117,890	178,330	242,044
Other	14,887	22,378	22,378	22,378
Current Liabilities	(91,736)	(10,484)	(10,484)	(10,484)
Creditors	(3,054)	(1,278)	(1,278)	(1,278)
Short term borrowings	(80,045)	0	0	0
Other	(8,637)	(9,205)	(9,205)	(9,205)
Long Term Liabilities	(9,047)	(9,555)	(9,555)	(9,555)
Long term borrowings	0	0	0	0
Other long term liabilities	(9,047)	(9,555)	(9,555)	(9,555)
Net Assets	97,784	129,793	190,283	254,047
Minority Interests	0	0	0	0
Shareholder equity	97,784	129,793	190,283	254,047
CASH FLOW				
Operating Cash Flow	(18,204)	71,519	60,490	63,765
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(29)	(16)	(50)	(50)
Acquisitions/disposals	0	0	0	0
Financing	0	0	0	0
Dividends	0	0	0	0
Other	(5,674)	(28,687)	0	0
Net Cash Flow	(23,907)	42,817	60,440	63,715
Opening net debt/(cash)	(104,849)	(80,942)	(117,891)	(178,330)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	0	(5,868)	(0)	0
Closing net debt/(cash)	(80,942)	(117,891)	(178,330)	(242,045)

Source: company reports, Edison Investment Research

Contact details	Revenue by geography
SIGA Technologies 31 East 62nd Street New York, NY 10065 (212) 672-9100 www.siga.com	

Management team

CEO: Phillip L Gomez, PhD

Phillip Gomez has served as SIGA's chief executive officer since 2016. Prior to joining SIGA, he was a principal in the Pharma & Life Sciences Management Consulting Practice at PwC and PRTM Management Consultants, where he led development and execution of business strategies for leading pharmaceutical companies, governmental agencies, academic medical centers and foundations. Dr Gomez joined PRTM from the Vaccine Research Center at the National Institute of Allergy and Infectious Diseases at the NIH, where he established the Vaccine Production Program against HIV, SARS, Ebola, West Nile Virus and influenza. Before that, he spent more than nine years in the pharmaceutical industry at Abbott Laboratories, Sanofi Pasteur and Baxter in positions of increasing responsibility, leading process/product development initiatives for the development of multiple biologics. Dr Gomez holds a BA degree from Dartmouth College, a PhD in chemical engineering from Lehigh University and an MBA from the Smith School of Business at the University of Maryland.

CSO: Dennis Hruby

Dennis Hruby has more than 25 years of experience in poxviruses, virology and anti-infective research. Dr Hruby serves as executive vice president and chief scientific officer, having served as SIGA's chief scientific officer since 2000. Before that, he was vice president of research and senior scientific adviser to SIGA. Dr Hruby conducted virology research as an NIH postdoctoral fellow at the University of Wisconsin, Madison and at the State University of New York, Stony Brook. He is a courtesy professor of microbiology at Oregon State University, after spending 27 years on the faculty and serving in a number of capacities, including director of the molecular and cellular biology program and chairman of the microbiology department. Dr Hruby received his PhD in microbiology from the University of Colorado Medical Center and holds an undergraduate degree in microbiology from Oregon State University. He has published more than 210 manuscripts/chapters, 400 abstracts and holds approximately 200 US and international patents.

CFO: Daniel J Luckshire

Daniel Luckshire joined as executive vice president and chief financial officer in 2011. Prior to joining SIGA, he was a strategic adviser and private investor for a broad range of companies who are leaders within specialized market segments. Between 1998 and 2008, Dan was an investment banker at Merrill Lynch & Co., where he held various positions of increasing responsibility. Before Merrill Lynch, he was a member of the management team that built USI Insurance Services into a national insurance brokerage and was a CPA at Price Waterhouse. Dan has an MBA degree in finance and strategic management from The Wharton School of the University of Pennsylvania and a bachelor of science degree in accountancy from Villanova University.

General counsel and CAO: Robin E Abrams

Robin Abrams has extensive expertise with nearly 20 years in senior legal roles in the pharmaceutical and biotechnology industries. She joined SIGA as general counsel and chief administrative officer in 2016, when she also assumed responsibilities as executive vice president and general counsel for vTv Therapeutics. Before joining SIGA, Robin was vice president and associate general counsel at Purdue Pharma where she was responsible for the company's federal and state government investigations and litigation, and oversaw the regulatory, employment, and compliance groups within the Law Department. Prior to Purdue, Robin served as an assistant US attorney in the Southern District of New York, rising to the position of deputy chief of the criminal division, and clerked for then-Chief Judge Jack B. Weinstein, federal District Court, Eastern District of New York. Robin earned her juris doctor degree from New York University School of Law, and her bachelor of arts degree from Cornell University.

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