October 2024

SIGA Technologies (SIGA)

Case Study by Thomas Giroux

Recommendation: (L) \$SIGA Price Target = \$18.92 *average of DCF and RV*

Estimated Total Returns: \approx **173.41%**

Brand	Indication	Approval	MOA	Admin	Economics	IP
TPOXX	Smallpox	Jul '18	VP37 Target	Oral	=	2032
IV TPOXX				IV	=	2032
Brand	Indication	Phase	MOA		Economics	IP
TPOXX	mpox	[VP37 Target	Oral	~2.9m	2032

millions USD, except per share						
Price	6.92					
Shares	71.37					
Mkt Cap	493.87					
Cash	115.90					
Debt	0.00					
EV	377.97					
DIC	007.50					
PIC	237.50					
AD	(69.95)					

Business Description:

SIGA Technologies is a biotech company incorporated in 1995 and headquartered in NYC with a lab facility in Corvallis, Oregon. They have a single drug, TPOXX, an antiviral drug to treat smallpox, mpox and many other orthopoxviruses. The mpox indication has not yet been FDA approved.

The Opportunity (α):

SIGA essentially has one customer, the U.S. Government (79% of sales) through BARDA and the DOD. Since the last reported case of smallpox was in the 70's, the U.S. Gov buys TPOXX for its Strategic National Stockpile (SNS) in the hopes of preventing potential bioterrorist attacks. However, given the efficacy of TPOXX in treating smallpox, the MHRA (UK) and the EMA (EU) have already approved the TPOXX mpox indication. The FDA and Health Canada, although

having already approved the smallpox indication, have yet to approve the mpox indication. <u>I</u> <u>STRONGLY believe that the indication will be approved by 2026.</u>

To assess the value of \$SIGA, I will forecast the:

- 1) value of future smallpox indication contract with the US Gov
- 2) value of mpox indication (based on potential deaths and cases)

Why TPOXX Will Get FDA Approved for mpox:

I believe the TPOXX mpox indication will get approved because:

- The indication is already approved in the UK and the EU
- Tecovirimat Used under (EA) to Treat Mpox in the U.S. ('22-'23)

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31 out of 55 immunocompromised patients did not experience poor outcomes (64.7%). One sample Z-Test at \alpha=0.05; z=(0.6471-0.5) / sqrt(0.5*(1-0.5)/51)\approx 2.10 Z-score = 2.10 and p-value = 0.0179. This shows statistically significant results for TPOXX
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- Tecovirimat targets the F13L gene product in orthopoxviruses, which is conserved in both smallpox and mpox viruses (refer to Fundamental Scientific Analysis on P.7)
- The CDC reported the use of tecovirimat for severe mpox cases during the 2022 outbreak

A clinical trial was conducted during Summer 2024 in the Democratic Republic of the Congo to assess the effectiveness of TPOXX against mpox. The primary endpoint was time to lesion resolution within 28 days post-randomization for patients with monkeypox. The study was a double-blind, randomized trial for TPOXX measured against placebo (n = 597). The primary endpoint <u>failed to be reached</u>, but results were slightly skewed when accounting for the shortened time patients were on the medication. In sum, I think the market is mispricing this trial.

Missing the primary endpoint is not entirely unexpected given that the study population was hospitalized during the duration of treatment receiving a high level of supportive care, and since many presented for treatment more than a week after their illness started <u>SIGA CEO Diem Nguyen on PALM007 mpox clinical trial results</u>

Mpox Indication Approval Effect on Share Price:

To value the mpox indication of mpox, I first predicted the potential number of people who would be infected (and potentially die) of mpox, until '26 which I believe is the expected date of approval. The mortality rate in my study is skewed, because of poor reporting of cases and deaths in Africa,

but the mortality rate I still used is 0.22% (observed death rate = $\sim 1\%$). I used the SUIR approach to forecast future cases of mpox by continent with the following equation:

$$N(t) = N(t-1) + min[S(t-1), I(t-1) * R_0 * b] - V(t-1)$$

Where:

N(t) = Cumulative number of cases at time t

N(t-1) = Cumulative number of cases at time t-1

S(t-1) = Number of susceptible individuals at time t-1

I(t-1) = Number of infected individuals at time t-1

 R_0 = Basic reproduction number (1.79 in the model)

 $b = Behavior\ change\ factor\ (0.85\ in\ the\ model)$

V(t-1) = Number of vaccinated individuals at time t-1

All the Value of Statistical Life (VSL) are from the OECD and observed cases data from Our World in Data

Mpox TAM + TPOXX Indication Valuation

Cummulative Data (May 1:	2022 - 9	Sept 10 2024)												
North America South America Europe		Africa		Asia	Oceania	World								
Confirmed Cases		40,804		24,079		27,628		8,302		5,450	714	106,977		
proportion %		38%		23%		26%		8%		5%	1%	100%		
Confirmed Deaths		101		47		9		55		22	0	234	234	
proportion %		43%		20%		4%		24%		9%	0%	100%		
Mortality %		0.25%		0.20%		0.03%		0.66%		0.40%	0.00%	0.22%		
TAM														
Gay Male Population		12,262,395	1	.7,424,470	:	14,895,137		15,151,350	99	9,007,261	921,774	159,662,387	7	
Potential Deaths		30,352		34,011		4,852		100,376		399,662	2,016	571,271		
SUIR '26 Target Cases		1,096,576		647,104		742,481	223,110 146,464		19,188	2,874,923				
SUIR '26 Target Deaths		2,714		1,263		242		1,478		591	0	6,289		
TPOXX mpox Valuation														
Projected '26 Cases		1,096,576		647,104		742,481		223,110		146,464	19,188	2,874,923		
Projected '26 Deaths		2,714		1,263		242		1,478		591	0	6,289		
VSL per region ('23)	\$	5,200,000	\$	1,900,000	\$	3,800,000	\$	900,000	\$	1,500,000	\$ 4,300,000			
Mortality cost savings	\$	14,114,338,218	\$ 2	2,399,867,485	\$	919,098,186	\$	1,330,273,690	\$ 8	386,849,126	\$ -	\$ 19,650,426,	705	
PV (@ 40% discount)	\$	7,201,192,969	\$ 1	,224,422,186	\$	468,927,646	\$	678,711,066	\$ 4	152,474,044	\$ -	\$ 10,025,727,	911	
PV per year	\$	5,012,863,955												
Mkt penetration		10%												
Revenue per year	\$	501,286,396				-								
Avg Net margin %		46%	pl	us mpox R&D	Proj	ected Total NI		Total NI po	er yea	ır				
NI per year	\$	230,591,742	\$	51,153,584	\$	512,337,068	\$			256,168,534				
		2022		2023		LTM		Total	ĺ					
R&D expenses	\$	22,525,642	\$	16,427,942	\$	12,200,000	\$	51,153,584						

From this model, I believe that the total future value of mortality cost savings worldwide is = \$19b, with an industry accurate discount rate of 40% the present value would be = \$10b

Other Potential ST Catalyst:

On Sept 19th of this year, the Chief Medical Officer (CMO) Jay Varma was fired following resurfaced videos of him discrediting the success of SIGA and underlining misleading ways the company utilizes the media to prop itself up. In the wake of this flamboyant and viral corporate debauchery, I believe the company will attract a valuable candidate to fill the CMO role (because it has a good hiring track record).

Stock Valuation:

From a relative valuation perspective, I compared biotech stocks with SIGA. However, there are no ~\$500m mkt cap profitable biotech stocks, which is why I had to use \$7b mkt cap stocks in the US. Please pay attention to the light blue \$BAVA.CO company (Bavarian Nordic stock, in Denmark), which is potentially the most pertinent comparable to SIGA, because the latter manufactures the JYNNEOS vaccine that treats mpox, with customers and contracting very similar to SIGA's.

Relative Valuation	n.														
OCT-3rd								ΠM	Oct-24			TTM		πм	
USD m's		Price	Shares	Market Cap	Cash	Funded Debt	EV	Revenue	P/E	EV/Sales	Price/Sales	R&D +SG&A	Op mrgn	FCF	FCF Yield
SIGA	\$	6.92	71.37	494	116	0	378	173	5.97	2.19	2.86	39	77%	74	15%
BAVA.CO	\$	33.27	77.80	6,053	321	18	5,749	874	24.34	6.58	6.93	376	57%	155	6%
JAZZ	\$	108.67	61.75	6,710	2,679	5,774	9,806	3,910	18.54	2.51	1.72	2,907	26%	1,017	15%
KRYS	\$	176.14	28.73	5,061	663	8	4,405	166	44.72	26.50	30.44	151	9%	(23)	-
HALO	\$	61.04	126.68	7,733	744	1,503	8,492	873	22.94	9.72	8.85	296	66%	408	5%
EXEL	\$	26.28	285.25	7,496	1,399	198	6,296	2,014	22.98	3.13	3.72	1,532	24%	166	2%
Mean (except SIGA)				6,611	1,161	1,500	6,950	1,567	26.70	9.69	10.33	1,052	36%	345	7%
Median				6,710	744	198	6,296	874	22.98	6.58	6.93	376	26%	166	6%
Implied Price		·		•					\$ 26.64	\$ 20.83	\$ 16.79			·	
									avg	\$ 21.42	210%				

From a DCF approach, **by totally disregarding TV and only conducting a 5-year projection**, I expect a share price of \$16.40.

My assumptions for the model are the following:

- Net margin in line with historicals = 46%
- Discount rate (Ke) = 9.21%

$$Ke = Rf + B(EqRP) = > 3.75\% + 0.91(6\%)$$

• Mpox indication approval in 2026

Revenue Projections

mpox approval

USD Ms	2025	2026	2027	2028	2029	
TPOXX smallpox	173.65	179.21	167.86	167.86	167.86	
TPOXX mpox	-	556.89	556.89	556.89		
R&D	4.85	5.01	5.17	5.34 5.5		
Total Revenue	178.50	741.11	729.92	730.09	730.26	
Y/Y growth %	3.20%	315.19%	-1.51%	0.02%	0.02%	
CAGR	32.55%					

Net Income

mpox approval

USD Ms	2025	2026	2027	2028	2029
TPOXX smallpox	79.88	82.44	77.22	77.22	77.22
TPOXX mpox	0.00	256.17	256.17	256.17	256.17
R&D	2.23	2.30	2.38	2.45	2.53
Net Income	82.11	340.91	335.76	335.84	335.92
Y/Y growth %	3.20%	315.19%	-1.51%	0.02%	0.02%
CAGR	32.55%				
-		-			
NPV	\$1,071.12				
Cash	106.95				
debt	0				
shares	71.75				
price	\$16.42	vs current price	\$ 6.92		
	137.27%				

I already explained my reasoning behind the \$256.17m/year mpox indication net income (P.4), but my forecasts regarding the future smallpox contract with the US Gov are listed below.

First, SIGA's CEO said this regarding the next US contract on the Q2 earnings call:

[...] based on our conversations with government officials as well as other SNS contracts to procure medical countermeasures, we are confident that the government is receptive to a new, long-dated contract, most likely between 5 and 10 years, and the aggregate value of this contract should surpass the aggregate value of our contract (\$546m signed in '18). SIGA Q2 Transcript (P.3, second paragraph)

Taking this information into account, we can forecast the next contract's value by using our base contract of \$546m and multiplying it by the budget increases of all the US Gov agencies that directly deal with SIGA:

usd Ms Government Agencies' Budgets Growth Since 2018

Base contract		SNS		CDP/military			BARDA		CDC		Average
\$	546	\$	891	\$	657	\$	1,265	\$	872	\$	921
	growth %		63.11%)	20.29%		131.73%		59.72%	•	

We can also multiply the base contract with economic growth and adjustments since 2018:

	usd Ms	grow	growth accounted for since 2018									
Ва	se contract	US	pop. Growth	G	uidance	US	S Budget Increase		Cummul. Infl	GD	P growth	Average
\$	546	\$	561.89	\$	563.47	\$	865.57	\$	684.14	\$	609.94	\$ 657
	growth %		2.91%		3.20%		58.53%		25.30%		11.71%	

I personally believe that only 3 variables are pertinent when forecasting the next US Gov contract: the BARDA budget increase since 2018, the US Military budget increase since 2018 and the Strategic National Stockpile (SNS) budget increase since 2018. The average estimated SIGA contract for smallpox would be \$1,007.13m and around \$167.86m per year (if we assume a 6-year contract like last time).

usd Ms

BARDA	\$ 1,265.24
US Budget Increa	\$ 865.57
SNS	\$ 890.58
Average	\$ 1,007.13
per year	\$ 167.86

Supplemental Info:

The increased lobbying expenditure by SIGA—65% higher than the inflation-adjusted amount before the 2018 contract—suggests that the new US government contract is likely to happen and be of higher aggregate value:

Lobbying spending in 2017, leading up to the signing of the 19C BARDA contract

19C BARDA Contract Signed on Sept 10, 2018

000's USD	infl.	Adj. (x1.25)			
03-Jan-17	20	25			
23-Jan-17	20	25		Date reported	Ammount
07-Apr-17	20	25		22-Jan-24	60
20-Apr-17	20	25		05-Feb-24	50
10-Jul-17	20	25		04-Apr-24	50
20-Jul-17	20	25		16-Apr-24	60
03-Oct-17	20	25		22-Jul-24	60
17-Oct-17	20	25		01-Aug-24	50
	160	200	VS		330

Fundamental Scientific Analysis (4 most pertinent studies):

1)

The sequence consistency of F13 between monkeypox and variola viruses ranges from 97.58% to 99.73%. AlphaFold2 created a reliable 3D model with a confidence score of 92.062. Tecovirimat libdock binding scores were 71.90 for monkeypox and 78.03 for variola, with binding energies of -10.65 and -38.68 kcal/mol, respectively. The active site was defined within a specific spherical region centered at coordinates X: -6.27702, Y: -2.48567, Z: -8.66086, with a radius of 8.9 Å.

The molecular docking results indicate that tecovirimat is effective against both monkeypox and variola viruses, providing insights into its binding mechanisms that could aid in treating monkeypox. F13 Predicted Full-Length Structure and Tecovirimat Binding Sites

2)

The study involved 549 monkeypox patients treated with tecovirimat. 99.8% received it orally, avoiding hospitalization. Among 369 patients (with available data), only 3.5% reported adverse events, mostly nonserious. Median time to symptom improvement was 3 days, regardless of HIV status, supporting ongoing use of tecovirimat for monkeypox treatment.

A case report detailed a 37-year-old immunosuppressed male with confirmed monkeypox. He received 600 mg of tecovirimat twice daily for two weeks, leading to rapid disappearance of skin lesions without significant negative effects. Efficacy of TPOXX Against Mpox

3)

The study evaluated tecovirimat (TCV) in nine adults (n = 9) with severe mpox in Montréal. Five patients experienced severe head and neck symptoms, while four had genitourinary or anorectal issues. Two-thirds received treatment for suspected bacterial superinfection. All patients, including

65%

five living with HIV, recovered within a median of nine days without adverse events or relapses. TCV was administered a median of nine days after symptom onset, and no patients discontinued treatment early. <u>Health Canada Study Conducted in Montréal, March 2023</u>

4)

This study assessed the compassionate use of tecovirimat in 25 (n = 25) male patients with monkeypox at UC Davis from June 3 to August 13, 2022. Participants had a median age of 40.7 years and received oral tecovirimat for 14 days. By day 7, 40% reported complete lesion resolution, and by day 21, 92% achieved resolution of lesions and pain. Adverse events included fatigue (28%), headache (20%), and nausea (16%), but all patients tolerated treatment well. <u>UC Davis, Summer 2022 Study on TPOXX Efficacy Against Mpox</u>

Summary of Scientific Analysis:

Tecovirimat (TPOXX) clearly demonstrates efficacy in treating monkeypox. Clinical evidence reveals rapid symptom improvement and high rates of lesion resolution, even in severe cases. Its well-tolerated profile, with minimal adverse events, reinforces its potential as a critical antiviral treatment, making it a promising option in managing monkeypox infections.