EDISON

SIGA Technologies

Financial update

Additional approvals expected shortly

Pharma & biotech

SIGA recently reported Q321 results, which featured $2.3m in oral TPOXX purchases by the Canadian Department of National Defence (CDND). Importantly, the US Biomedical Advanced Research and Development Authority (BARDA) has exercised its procurement option valued at $112.5m, with product deliveries targeted to occur by the end of 2021 (approximately 30% of the procured product was delivered in October alone). The company, however, has indicated that COVID-19 related supply chain issues may delay some of the deliveries, though it is working diligently to avoid that.

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	9.0	N/A
12/21e	133.3	87.4	0.88	0.0	8.4	N/A
12/22e	124.7	78.5	0.80	0.0	9.3	N/A

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

IV TPOXX approval targeted for Q122

In April, SIGA announced it had filed an NDA with the FDA for the intravenous (iv) formulation of TPOXX. The iv formulation would be used 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. The company is currently estimating Q122 for approval.

EMA and Canada approvals expected by Q122

SIGA submitted an application to the European Medicines Agency (EMA) in July 2020 for oral TPOXX covering all human pathogenic orthopoxviruses, including smallpox, monkeypox, cowpox and complications from vaccinia. In December 2020, the company also filed for marketing authorization for oral TPOXX in Canada. The review process in both jurisdictions is expected to be completed by Q122.

Additional international sales order in the works

SIGA is partnered with Meridian Medical Technologies, a Pfizer subsidiary focused on health security, for the international marketing of TPOXX. So far two separate contracts with the Canadian government for the delivery of up to $47m worth (combined) of TPOXX have been signed and the companies are working on other markets. SIGA is currently working on an order from an additional jurisdiction though precise timing is unknown due to COVID-19.

Valuation: $940m or $12.68 per share

We have adjusted our SIGA valuation to $940m or $12.68 per share from $949m or $12.65 per share. The decline in the total valuation is due to lower net cash, mainly attributable to the stock buyback, while a lower number of outstanding shares has increased the per-share valuation. We expect a significant increase in cash levels once the 2021 BARDA deliveries are completed.

9 November 2021

Price	**US$7.4**
Market cap	**US$548m**

Net cash ($m) at 30 September 2021	92.8
Shares in issue	74.1m
Free float	54.8%
Code	SIGA
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	4.4	18.5	3.5
Rel (local)	(2.5)	11.82	(22.8)
52-week high/low	US$7.8	US$5.7	

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

Oral TPOXX Canadian regulatory approval	Late 2021/early 2022
Oral TPOXX EMA regulatory approval	Q122
Iv TPOXX FDA approval	Q122

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Edison profile page

Q321 results

SIGA recently reported Q321 results, which featured $2.3m of international revenue related to oral TPOXX purchases by the CDND. Total revenues were $4.8m for the quarter and included $2.5m in revenue in connection with government funded research activities (which mostly offset R&D expenses). With the exercise of the BARDA option valued at $112.5m, the company is diligently working on completing deliveries by the end of the year and approximately 30% were delivered in October.

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 smallpox 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 filed in April 2021 with approval expected Q122.
	US	Liquid (powder for re-constitution)	Treatment of smallpox in people weighing <13kg (children)	Two leading formulations have been transitioned to CRO partner for adaptive pharmacokinetic clinical trials. Development fully funded by BARDA.
	US	Oral	Post-exposure prophylaxis (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. TPOXX+Jynneos study expected to begin enrolment in Q421 (with data in H222) while the safety study expected to begin in Q122.
	EU	Oral	Treatment of all human pathogenic orthopoxviruses (smallpox, monkeypox, cowpox, vaccinia) in those weighing >13kg	MAA submission July 2020. Approval expected Q122.
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.
ZEMDRI	US	IV	Biodefense	Partnership with ZEMDRI's manufacturer Cipla was announced in March 2021. SIGA will help Cipla obtain a BARDA contract for a biodefense indication.

Source: SIGA Technologies

With regards to expanding beyond the current oral TPOXX approval, iv TPOXX is under active review by the FDA with approval targeted for Q122. As a reminder, the iv formulation would be used 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, the company had previously filed with the EMA and Health Canada for approval. The EMA approval would cover all human orthopoxvirus pathogens and is expected in Q122 (the company has already responded to the 180-day questions from the agency). The Health Canada approval would cover oral TPOXX for the treatment of smallpox and is expected by Q122 though could come as soon as late Q421.

One of the most important development programs at SIGA is the post-exposure prophylaxis (PEP) label expansion. 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).[1] 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].'

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 and FDA have come to an agreement on trial design and two human studies are planned. There will be an immunogenicity trial to evaluate if there is interference with the Jynneos smallpox vaccine and a 28-day safety study. The Jynneos study is expected to begin in Q421 and provide data in H222, while the safety study is expected to begin in Q122 (no timing on data has been announced).

Additionally, the company announced it has completed a post-marketing commitment to study the pharmacokinetics of oral TPOXX in people weighing over 120kg (approximately 13% of the US population). Based on these results, the TPOXX label is likely to be modified to recommend a dosage of 600mg three times daily for those weighing over 120kg (the current label recommends 600mg twice daily). Note that this labelling change would reduce the number of effective courses in the strategic national stockpile and could lead the US government to increase its orders to make up for that at some point in the future.

Valuation

We have adjusted our SIGA valuation to $940m or $12.68 per share, from $949m or $12.65 per share. The decline in the total valuation is due to lower net cash, mainly attributable to the stock buyback, while a lower number of outstanding shares has increased the per-share valuation. We expect a significant increase in cash levels once the 2021 BARDA deliveries are completed.

Exhibit 2: SIGA valuation table

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	439
TPOXX Canada	Treatment of smallpox	On market	100%	2020	11	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						847
Net cash (Q321) ($m)						92.82
Total firm value ($m)						**940**
Total basic shares (m)						74.1
Value per basic share ($)						**12.68**

Source: Edison Investment Research

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

Financials

Following Q321 results and the announcement of the BARDA option, we have increased our FY21 revenue estimate by $14.1m. Our FY22 revenue estimate has also increased by $0.3m due to higher R&D revenues (which, as mentioned, mainly offset R&D expenses). We have also increased our operating expense estimates by $0.7m for both FY21 and FY22 due to slightly higher run rates. SIGA reported $92.8m in cash at the end of September. We currently forecast $163.3m in cash at the end of the year, assuming all payments for BARDA deliveries are made by then, though this estimate does not take into account additional stock repurchases.

SIGA is currently working through a $50m stock repurchase program, which was announced in March 2020 and runs through the end of 2021. So far, 7.7m shares have been repurchased for approximately $49m, including $7.1m in Q321. In August 2021 the company announced an additional $50m share repurchase program, which will run through the end of 2023. Shares under the new plan can be repurchased either once the current plan expires or once the maximum amount has been utilized.

Exhibit 3: Financial summary

$000s	2019	2020	2021e	2022e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	26,742	124,959	133,313	124,730
Cost of Sales	(1,783)	(14,797)	(15,955)	(15,956)
Gross Profit	24,959	110,162	117,358	108,773
Research & Development	(13,303)	(10,939)	(11,361)	(11,474)
General & Administrative	(13,978)	(14,722)	(18,630)	(18,816)
EBITDA	(27)	84,503	87,314	77,953
Operating Profit (before amort. and except.)	500	85,033	87,444	78,483
Intangible amortization	0	0	0	0
Other	2,822	532	76	0
Exceptionals	5,091	(8,507)	295	0
Operating Profit	5,591	76,525	87,738	78,483
Net Interest	(15,770)	(3,017)	0	0
Other	0	0	0	0
Profit Before Tax (norm)	(15,270)	82,016	87,444	78,483
Profit Before Tax (reported)	(10,178)	73,509	87,738	78,483
Tax	2,937	(17,167)	(21,347)	(18,836)
Deferred tax	0	0	0	0
Profit After Tax (norm)	(12,332)	64,849	66,097	59,647
Profit After Tax (reported)	(7,241)	56,342	66,392	59,647
Average Number of Shares Outstanding (m)	81.0	79.3	75.4	74.1
EPS - normalized ($)	(0.15)	0.82	0.88	0.80
EPS - reported ($)	(0.09)	0.71	0.88	0.80
Dividend per share ($)	0.00	0.00	0.00	0.00
Gross Margin (%)	93.3	88.2	88.0	87.2
EBITDA Margin (%)	-0.1	67.6	65.5	62.5
Operating Margin (before GW and except.) (%)	1.9	68.0	65.6	62.9
BALANCE SHEET				
Fixed Assets	18,524	6,223	6,626	6,676
Intangible Assets	898	898	898	898
Tangible Assets	2,618	2,104	2,468	2,518
Other	15,008	3,221	3,259	3,259
Current Assets	180,042	143,608	199,458	260,778
Stocks	0	0	0	0
Debtors	4,168	3,340	3,823	3,823
Cash	160,987	117,890	163,340	224,660
Other	14,887	22,378	32,295	32,295
Current Liabilities	(91,736)	(10,484)	(18,942)	(18,942)
Creditors	(3,054)	(1,278)	(9,963)	(9,963)
Short term borrowings	(80,045)	0	0	0
Other	(8,637)	(9,205)	(8,979)	(8,979)
Long Term Liabilities	(9,047)	(9,555)	(9,555)	(10,065)
Long term borrowings	0	0	0	0
Other long term liabilities	(9,047)	(9,555)	(9,555)	(10,065)
Net Assets	97,784	129,793	177,587	238,447
Minority Interests	0	0	0	0
Shareholder equity	97,784	129,793	177,587	238,447
CASH FLOW				
Operating Cash Flow	(18,204)	71,519	65,912	61,371
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(29)	(16)	(24)	(50)
Acquisitions/disposals	0	0	0	0
Financing	0	0	0	0
Dividends	0	0	0	0
Other	(5,674)	(28,687)	(13,143)	0
Net Cash Flow	(23,907)	42,817	52,745	61,321
Opening net debt/(cash)	(104,849)	(80,942)	(117,891)	(163,339)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	0	(5,868)	(7,296)	(0)
Closing net debt/(cash)	(80,942)	(117,891)	(163,339)	(224,660)

Source: company reports, Edison Investment Research

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