SIGA Technologies

Q123 update

US stockpiles front and center in Q1 and FY23

Pharma and biotech

SIGA's Q123 results were largely driven by US TPOXX deliveries under existing contracts. Q123 product revenues of $5.7m ($7.3m in Q122) were primarily attributed to $5.1m in TPOXX deliveries to the US Department of Defense (DoD). An additional $2.6m in R&D-related income took total revenue to $8.3m (down 21% y-o-y). While TPOXX deliveries (oral and intravenous, IV) to the US strategic national stockpile and international expansion remain key growth areas, the potential post-exposure prophylactic (PEP) label expansion following the projected data readout within the next two months (FDA submission targeted for early 2024) is anticipated to be the next key revenue growth catalyst. With a longer duration of treatment required (28 days versus 14 for smallpox), the PEP opportunity could materially expand SIGA's addressable market, in our view. SIGA remains well capitalized (end-Q123 cash of $115.7m), resulting in the company announcing a special cash dividend of $0.45/share, payable in June 2023. We now obtain a valuation of $17.53/share (ex-dividend), from $17.70/share previously.

Year end	Revenue (US$m)	EBITDA* (US$m)	PBT* (US$m)	EPS* (US$)	P/E (x)	Net cash (US$m)
12/21	133.7	89.7	89.1	0.92	6.4	103.1
12/22	110.8	44.3	42.7	0.45	13.1	98.8
12/23e	175.2	97.2	96.7	1.05	5.6	110.7
12/24e	181.0	102.3	101.8	1.16	5.1	164.5

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

FY23 BARDA deliveries in sight

In Q123, SIGA recorded $8.3m in revenue (vs $10.5m in Q122), mainly led by oral TPOXX deliveries ($5.1m) to the US DoD and R&D-related revenue ($2.6m) from the government-sponsored PEP label program. We project strong top-line performance in FY23, driven by anticipated oral and IV TPOXX deliveries (worth $113m and $26m, respectively) under the 19C BARDA contract, the pending $5.5m in deliveries to the US DoD and $8m from international orders (including $7m of orders contracted but not delivered in FY22). Further upside could come from any additional orders received through FY23.

PEP trial data readout a crucial upcoming milestone

With patient enrolment for both immunogenicity and expanded safety trials under the PEP label expansion program complete, we expect all eyes to be focused on data readouts, expected within the next two months. If favourable, this should lead to a supplementary new drug application by early 2024, followed by a possible initiation of PEP sales in 2025.

Valuation: Adjusts to $17.53 per share (ex-dividend)

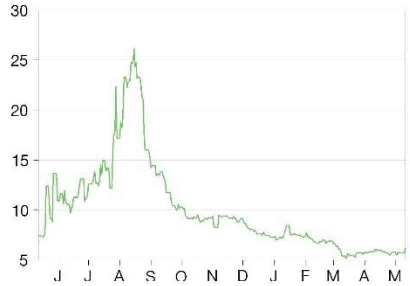
SIGA ended Q123 with a strong balance sheet, allowing it to announce a [$32.1m ($0.45/share) cash dividend (similar to FY22)]. The 8% dividend yield, in particular, is encouraging, given the current macro market environment. Incorporating the ex-dividend cash balance ($83.6m), lower share count (71.3m vs 72.2m previously), and slight tweaks to our FY23 and FY24 estimates, we have adjusted our valuation (ex-dividend) to $1.25bn ($17.53/share), from $1.28m ($17.7/share).

15 May 2023

Price	**US$5.9**
Market cap	**US$421m**

Net cash ($m) at 31 March 2023 (adjusted to reflect expected payment of FY23 dividend)	83.6
Shares in issue (as of April 2023)	71.3m
Free float	56%
Code	SIGA
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	0.0	(13.0)	(20.4)
Rel (local)	(0.8)	(13.7)	(24.1)
52-week high/low		US$26.15	US$5.23

Business description

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

Next events

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Financials

SIGA reported total revenue of $8.3m in Q123, of which $5.7m ($7.3m in Q122) were product-related revenues, primarily attributed to oral TPOXX deliveries for the existing US DoD contract ($5.1m of the total $10.7m order). The Q122 product revenues in comparison were related to sales of IV TPOXX to the US government under the 19C BARDA contract. R&D-related revenue was also lower year-on-year in the quarter ($2.6m vs $3.2m in Q122) and was primarily related to a change in the estimated profitability of the PEP label expansion R&D contract. Based on the upcoming expirations in the US strategic national stockpile, we continue to estimate oral TPOXX deliveries for BARDA of $112.5m each in FY23 and FY24. Additionally, we anticipate upside from international oral TPOXX orders of c $8m (including $1m or oral TPOXX delivered in April 2023 and $7m in pending order deliveries for contracts signed in FY22 and to be delivered by July 2023) and IV TPOXX orders worth c $26m, to be fulfilled during the year. We also expect the pending $5.5m of deliveries under the original $10.7m DoD contract (oral TPOXX worth $5.1m delivered in Q123) to materialise in FY23. Though we expect a strong operating performance in FY23 and FY24, we note the possibility of variability in timings of these orders.

Gross profit on product sale for the period improved to $4.6m from $2.6m (Q122), due to a significant decline in cost of sales ($1.2m in Q123 vs $4.7m in Q122), primarily related to lower manufacturing cost associated with oral TPOXX deliveries during the quarter as compared to IV TPOXX deliveries in Q122. We note that stockpile orders for oral TPOXX under the 19c BARDA contract have a relatively higher margin (c 85% gross margin) versus IV TPOXX (less than 40% gross margin).

Operating loss for the quarter came in at $2.1m in Q123 ($1.4m in Q122). Of the total operating expenses, R&D expenses rose to $5.0m (Q123) from $3.5m (Q122) due to higher fees for EMA regulatory submissions and increased vendor-related expenses for the PEP label expansion study and BARDA contract, which could not be fully offset by the R&D revenue recognized during the quarter. SG&A expenses were up 14.1% y-o-y to $4.2m, primarily due to higher professional service fees. SIGA recorded net loss of $0.9m in Q123 compared to $0.4m in Q122.

We make minor adjustments to our revenue forecasts, deferring some of the anticipated deliveries under the Canadian Department of National Defence's option (until 31 March 2024) to purchase up to $6m of additional oral TPOXX. We now forecast FY23 and FY24 revenue of $175m and $181m versus $176m and $177m, respectively. Our revised estimates for operating profit are $96.7m and $101.8m ($97.6m and $98.8m previously) for FY23 and FY24, respectively.

Valuation

We value SIGA on a risk-adjusted NPV basis for its various programs and contracts, forecasting to the end of the patent life in each geography. Our updated valuation for SIGA stands at $1.25bn or $17.53 per share ($1.28bn or $17.70/share previously). Incorporating the discussed changes to our estimates, rolling forward our model and incorporating the updated net cash figure (adjusted for the $0.45/share cash dividend announced post-period) has resulted in our valuation re-adjusting to $1.25bn or $17.53 per share from $1.28bn or $17.70/share previously.

Exhibit 1: SIGA's 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	123	363
TPOXX Canada	Treatment of smallpox	On market	100%	2020	19	49
TPOXX US IV and pediatric formulations	Treatment of smallpox	IV (NDA approved May 2022), pediatric (being formulated)	60–100%	2022–25	30	29
TPOXX US PEP	Post-exposure prophylaxis following exposure to smallpox	Development	50%	2025	128	234
TPOXX EU, Japan, Korea, Australia	Treatment of smallpox	EMA approved	55%	2022	346	223
Commercialization of TPOXX, PEP. US, Canada, Europe, Asia	Treatment of mpox			2024	173	269
Total						**1,166**
Pro-forma net cash (Q123) ($m)						83.6
Total firm value ($m)						1,249
Total basic shares (m) outstanding						71.3
Value per basic share ($)						**$17.53**

Source: Edison Investment Research

SIGA ended Q123 with a healthy net cash balance of $115.7m, which enabled it to declare a $0.45/share special cash dividend in May 2023. At the current outstanding share count of 71.3m, this comes to a payout of $32.1m and translates to a healthy 8% dividend yield and a payout ratio of c 44% of our projected FY23 net income of $73.5m. The dividend is payable on 1 June 2023 to shareholders of record at the close of business on 16 May 2023. We note that the company announced a similar dividend payout in May 2022, highlighting sustained balance sheet strength. This is particularly encouraging given the recent challenging macroeconomic environment for the biotech sector. We do note that SIGA is a commercial-stage, revenue generating company, which differentiates it from the typical development-stage or non-profitable biotechs. SIGA also continued share buybacks in Q123 and we calculate a total 1.14m shares bought back in the quarter for $7.6m. We note that (including the recent dividend declaration) the company has spent close to $150m in capital management since early 2020.

Note that our current valuation of SIGA ($17.53/share) incorporates pro-forma cash that is ex-dividend ($83.6m) and therefore investors may consider the incremental income from dividends (in addition to the expected capital gains) while evaluating return potential from the business. However, it is uncertain if the company expects to provide similar payouts in future years.

Mpox still a potential opportunity, albeit uncertain timing

In our last note, we had highlighted the US Centers for Disease Control and Prevention cautioning regarding mpox (monkeypox) recurrence and possible future outbreaks, and emphasizing the importance of being prepared. Despite the waning numbers globally, an increased number of cases has been reported recently in certain Asian countries such as Japan, South Korea and China. While not alarming, this highlights the continued latent threat of future escalations and therefore the ongoing requirement for both preventative vaccines and therapeutics, such as TPOXX, which is currently the only antiviral treatment approved for treatment of all orthopoxvirus pathogens, including mpox, in both the UK (July 2022) and the European Union (January 2022).

TPOXX has been used to treat more than 6,900 mpox patients in the United States on a compassionate basis and SIGA is participating in a total of nine trials (Q322 onwards) to assess the safety and efficacy of TPOXX in participants with mpox (the trials are required to receive regulatory approval from the US FDA). Five of these are randomized, placebo-controlled clinical trials and, as per latest available information, 175 patients have been enrolled across the studies. The pace of recruitment has been hindered by the reducing caseload globally, creating uncertainty in terms of full enrolment, readouts and FDA submission. SIGA has highlighted possible discussions with regulators to allow pooling of interim data from various studies as an alternative to completing the originally planned enrolment targets from a single study. If things progress of this front, it may allow for faster regulatory submission.

Exhibit 2: Financial summary

$000s	2020	2021	2022	2023e	2024e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	124,959	133,670	110,776	175,159	180,974
Of which Product revenue	115,471	126,803	86,662	154,684	160,294
Of which R&D revenue	9,488	6,868	24,114	20,476	20,681
Cost of Sales	(14,797)	(16,602)	(10,433)	(34,391)	(33,059)
Gross Profit on product sales	100,674	110,201	76,229	120,293	127,235
Research & Development	(10,939)	(9,942)	(22,526)	(22,751)	(22,978)
General & Administrative	(14,722)	(18,034)	(35,117)	(21,360)	(23,123)
EBITDA	88,579	89,716	44,250	97,183	102,338
Operating Profit (before amort. and excepts.)	84,501	89,093	42,700	96,658	101,814
Intangible Amortisation	-	-	-	-	-
Other	532	101	1,032	-	-
Exceptionals	(8,507)	118	401	-	-
Reported operating Profit	76,525	89,312	44,133	96,658	101,814
Net Interest	(3,017)	-	-	-	-
Other	-	-	-	-	-
Profit Before Tax (norm)	81,484	89,093	42,700	96,658	101,814
Profit Before Tax (reported)	73,509	89,312	44,133	96,658	101,814
Tax	(17,167)	(19,861)	(10,228)	(23,198)	(24,435)
Deferred tax	-	-	-	-	-
Profit After Tax (norm)	64,317	69,232	32,472	73,460	77,379
Profit After Tax (reported)	56,342	69,451	33,905	73,460	77,379
Average Number of Shares Outstanding (m)	79	75	73	70	67
EPS - normalized ($), basic	0.81	0.92	0.45	1.05	1.16
EPS - normalised fully diluted (c)	80.97	90.61	44.15	104.47	114.90
EPS - reported ($)	0.70	0.92	0.46	1.05	1.16
Gross Margin (%)	87	87	88	78	79
EBITDA Margin (%)	71	67	40	55	57
Operating Margin (before GW and except.) (%)	68	67	39	55	56
BALANCE SHEET					
Fixed Assets	6,223	5,973	9,250	10,659	10,134
Intangible Assets	898	898	898	898	898
Tangible Assets	2,104	2,366	1,848	1,324	799
Other	3,221	2,709	6,503	8,437	8,437
Current Assets	143,608	208,753	185,786	208,014	269,068
Stocks	-	19,510	39,273	43,200	45,360
Debtors	3,340	83,650	45,407	49,948	54,942
Cash	117,890	103,139	98,791	110,733	164,482
Other	22,378	2,453	2,316	4,133	4,283
Current Liabilities	(10,484)	(30,488)	(21,518)	(20,730)	(20,846)
Creditors	(1,278)	(2,028)	(3,355)	(2,568)	(2,683)
Short term borrowings	-	-	-	-	-
Other	(9,205)	(28,460)	(18,162)	(18,162)	(18,162)
Long Term Liabilities	(9,555)	(9,924)	(3,358)	(3,358)	(3,358)
Long term borrowings	-	-	-	-	-
Other long term liabilities	(9,555)	(9,924)	(3,358)	(3,358)	(3,358)
Net Assets	129,793	174,314	170,160	194,585	254,998
Minority Interests	-	-	-	-	-
Shareholder equity	129,793	174,314	170,160	194,585	254,998
CASH FLOW					
Operating Cash Flow	71,519	11,495	41,611	62,613	72,349
Net Interest	-	-	-	-	-
Tax	-	-	-	-	-
Capex	(16)	(51)	-	-	-
Acquisitions/disposals	-	-	-	-	-
Financing	-	-	-	-	-
Dividends	-	-	(32,940)	(32,071)	-
Other (including share buybacks)	(114,600)	(26,195)	(13,019)	(18,600)	(18,600)
Net Cash Flow	(43,097)	(14,751)	(4,348)	11,942	53,749
Opening net debt/(cash)	(80,942)	(117,890)	(103,139)	(98,791)	(110,733)
HP finance leases initiated	-	-	-	-	-
Exchange rate movements	-	-	-	-	-
Other	80,045	0	0	0	0
Closing net debt/(cash)	(117,890)	(103,139)	(98,791)	(110,733)	(164,482)

Source: Company reports, Edison Investment Research