April 24, 2019

# Tiziana Life Sciences (TLSA - \$6.89)

Favorable IDMC Interim Safety Review for Milciclib, Key Near Term Data Readouts.

Before the open, TLSA announced results from the interim safety review conducted by the Independent Data Monitoring Committee (IDMC) on 3/21/19. As toxicity often represents a significant obstacle, we are encouraged that the administration of milciclib (orally bioavailable, small molecule broad spectrum CDK inhibitor) for HCC wasn't associated with unexpected signs of toxicity. Eighty percent (8/10) of patients who completed treatment within the trial's timeframe requested to continue treatment under compassionate use, which is a positive, in our opinion. As a reminder, this Phase 2a clinical trial is a single-arm, repeated-dose (100mg 1x/day; four days on, three days off every four weeks for each cycle), for six months. The goal was to evaluate safety, tolerability and anti-tumor activity of milciclib in Sorafenib-refractory or intolerant patients with unresectable or metastatic advanced HCC (n=31). We were particularly encouraged that three of the seven patients approved to continue with treatment under compassionate use have completed 9, 13, and 16 months of treatment with milciclib. With 10 of 27 patients having completed the study, TLSA expects topline data to readout in 3Q19. We view milciclib as relatively de-risked since it hit primary endpoints in two previous Phase 2 trials in Thymic Carcinoma and Thymoma. These safety and clinical activity results are consistent with earlier reported LT safety and clinical activity data. We believe Foralumab (fully-human anti CD3 mAb for autoimmune and inflammatory diseases like NASH) represents TLSA's main value driver and expect their Phase 1 (intranasal delivery) for patients with MS to readout this quarter (2Q19). Additionally, we expect their Phase 1 oral Foralumab trial to readout in 2H19 and maintain that, although early, their programs are relatively de-risked since previous orally administered anti-CD3 mAb (OKT3) in NASH and T2D patients showed encouraging immunological trends (increase in Treg and anti-inflammatory markers). With catalysts around the corner, we are reiterating our Buy rating and \$17 price target.

- Encouraging IDMC review, 80% of patients requested to continue treatment. On top of strong safety, we were particularly encouraged by the amount of patients opting for compassionate use and the duration of treatment.
- **Important Catalysts around the corner.** We look forward to Foralumab MS readout in 2Q19 as well as topline milciclib in 3Q19.
- **Reiterating Buy rating and \$17 PT.** Our PT is based on Foralumab royalties at \$12.5/share; Milciclib royalties at \$3/share; cash (end'19) and tech value at \$1.5/share.

## Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY19E	(0.22)	(0.20)	(0.23)	(0.22)	(0.87)	NA
FY18E	(x.xx)	(x.xx)	(x.xx)	(0.17)E	(0.59)	NA
FY17A	(x.xx)	(x.xx)	(x.xx)	(x.xx)	(0.09)	NA
FY16A	(x.xx)	(x.xx)	(x.xx)	(x.xx)	(0.11)	NA

Source: Laidlaw & Company estimates

## Healthcare / Biotechnology

Ticker:	TSLA
Rating:	Buy
Price Target:	\$17.00

#### **Trading Data:**

Last Price (04/24/2019)	\$6.89
52-Week High (11/21/2018)	\$12.17
52-Week Low (04/01/2019)	\$5.00
Market Cap. (MM)	\$105.3
Shares Out. (MM)	126.1

#### Analyst

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Figure 1: Sum-of-the-Parts Analysis

Sum-of-the-parts valuation		
Segment	Valuation	Per share
	(000's)	value
Foralumab US royalties	\$166,623	\$11.00
Foralumab EY royalties	\$20,585	\$1.50
Milciclib WW royalties	\$46,491	\$3.00
Cash (end '19) & tech value	\$23,941	\$1.50
	\$237,055	\$17.00
2019 fully diluted shares out (000)		14,991

Source: Company Reports; Laidlaw and Company estimates

Tiziana Life Sciences
Potential clinical trial timeline estimates

2017A 2018E 2019E 2020E 2021E 2022E

10A 20A 30A 40A 10E 20E 30E 40E 10E 20E 30E 40E 10E 20E 30E 40E

Poralumab (TZLS-401)
Phase 1 in healthy volunteers with oral for NASH
Phase 2
Phase 3

Phase 1 in healthy volunteers with intranasal
Phase 2
Phase 3

Phase 3

**Figure 2: Potential Clinical Trials Timeline** 

Source: Company Reports; Laidlaw & Company estimates

Phase 2b combination therapy (milciclib + sorafenib) in HCC

Milciclib (TZLS-201)

Phase 2a monotherapy in HCC

Phase 3 mono Phase 3 combo

Figure 3: Quarterly Income Statement

Tiziana Life Sciences										
Quarterly income statement										
,		201	0.4	1	20404		201	<b>^</b>		2019E
(\$000 event per chare)	404			405	2018A	405			405	
(\$000 except per share)	<u>1QA</u>	2QE	3QE	4QE	<u>Year</u>	<u>1QE</u>	2QE	3QE	4QE	<u>Year</u>
Revenues										
Total Revenue										
Expenses:										
COGS (% of US Revenue)										
Gross Margin										
G&A	(1,083)	(1,083)	(1,126)	(1,126)	(4,417)	(1,500)	(1,500)	(1,750)	(1,750)	(6,500)
R&D	(1,569)	(1,569)	(1,186)	(1,186)	(5,510)	(1,500)	(1,500)	(1,750)	(1,750)	(6,500)
Total operating expenses	(2,652)	(2,652)	(2,312)	(2,312)	(9,927)	(3,000)	(3,000)	(3,500)	(3,500)	(13,000)
Operating income										
other income (expense)					(12)					
Loss before income tax	(2,652)	(2,652)	(2,312)	(2,312)	(9,939)	(3,000)	(3,000)	(3,500)	(3,500)	(13,000
Interest expense										
Provision (benefit) for income tax					1,945					
Net loss	(2,652)	(2,652)	(2,312)	(2,312)	(7,994)	(3,000)	(3,000)	(3,500)	(3,500)	(13,000)
Foreign currency					(20)					
Adj. NI/(loss)	(2,652)	(2,652)	(2,312)	(2,312)	(8,014)	(3,000)	(3,000)	(3,500)	(3,500)	(13,000)
NI/(loss) as reported					(8,014)					
Earning per Share (EPS)					(\$0.59)					
Adj EPS ex-1x & non-cash				(\$0.17)	(\$0.59)	(\$0.22)	(\$0.20)	(\$0.23)	(\$0.22)	(\$0.87
Weighted avg. shares (000)				13,641	13,646	13,841	15,174	15,374	15,574	14,991
Fully diluted shares (000)	-	-	-	13,641	13,646	13,841	15,174	15,374	15,574	14,991

Source: Company Reports; Laidlaw & Company estimates

Figure 4: Annual Income Statement

Tiziana Life Sciences Annual income statement					
(\$000's except per share)	2016A	2017A	2018E	2019E	2020E
Revenues					_
Total sales	\$0	\$0	\$0	\$0	\$0
COGS	0	0	0	0	0
Gross margin	0	0	0	0	0
R&D	(4,007)	(6,015)	(5,510)	(6,500)	(9,500)
G&A	(5,872)	(4,601)	(4,417)	(6,500)	(9,000)
Adj. Net Income	(9,120)	(8,646)	(8,014)	(13,000)	(18,500)
NI/(loss) as reported	(9,770)				
Adj-EPS ex-non-cash EPS as reported	(\$0.11) (\$0.11)	(\$0.09) (\$0.09)	(\$0.59)	(\$0.87)	(\$1.11)
Shares out (000) Fully diluted shares (000)	82,909 82,909	96,067 96,067	13,646 13,646	14,991 14,991	16,724 16,724

Source: Company Reports; Laidlaw & Company estimates

# Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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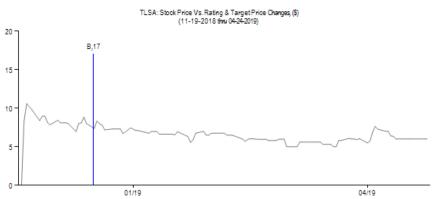
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# **RATINGS INFORMATION**

# Rating and Price Target Change History





Source: Laidlaw & Company Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage	% of Companies for which Laidlaw & Company has performed services for in the last 12 months		
		With This Rating	Investment Banking	Brokerage	
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%	
Buy (B)	Expected to outperform the sector average over 12 months.	63.49%	23.81%	3.17%	
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.35%	3.17%	0.00%	
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%	

#### ADDITIONAL COMPANIES MENTIONED

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