

## Tiziana Life Sciences (TLSA - \$5.00)

Healthcare / Biotechnology

### NASH in the Limelight, Plenty of Room for Improvement

We recently held a KOL event with both a leading hepatologist and an immunologist geared around TLSA's main value driver, Foralumab (fully human anti-CD3 oral mAb), as a potential treatment for large unmet medical needs such as NASH. As 2019 marks the first round of NASH pivotal readouts, these are exciting times for the field. After the recent unsuccessful GILD and positive ICPT's Phase 3 readouts, our KOL looks forward to GNFT's and AGN's upcoming readouts around YE19. He also emphasized the importance of the upcoming Phase 2b trial readouts from Cirius and Novo Nordisk in 2020. Although our KOL believes ICPT's OCA seems poised to be the first to cross the finish line with encouraging improvement in fibrosis data (most important endpoint, in his opinion); he concluded that there was plenty of room for improvement as pruritus appears to be a class effect of FXRs. He looks forward to additional data disclosed at EASL (April 10<sup>th</sup>-14<sup>th</sup>) in order to better understand NASH resolution flatness as well as AE control (LDLs and pruritus). As commercial viability is a point of interest, there seems to be clear heterogeneity within the disease depending on its stage of progression, which should ultimately lead to combination therapy. Our KOLs are particularly impressed with TLSA's targeted approach to inflammation. They compare it to using a scalpel vs. a hammer in order to rebalance the inflammatory process with lower chances of immunosuppression. As cellular debris accumulates, inflammation ensues, followed by a fibrogenic response. As opposed to steroids (giant mallet), Foralumab (oral mAb) could enable physiologic immunomodulation through Tregs in order to tone down the inflammatory response to the metabolic injury, potentially helping the fibrotic response. Foralumab's natural route (oral and nasal) remains the key to prevention of immunosuppression and we view TLSA's NASH trial as relatively de-risked since an oral fully murine OKT3 Phase 2 trial showed encouraging trends in NASH patients. We are reiterating our Buy rating and \$17 price target.

- **Encouraging developments, plenty of room for improvement.** As ICPT's successful interim Phase 3 look provided significant progress in this highly competitive field, AEs and NASH resolution results leaves room for improvement.
- **Foralumab, a novel relatively de-risked option for combination therapy.** Although seemingly early, we continue to view Foralumab as relatively de-risked since fully murine oral OKT3 previously demonstrated encouraging immunological trends in a Phase 2 trial in NASH patients.
- **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
<b>FY19E</b>	(0.18)	(0.18)	(0.20)	(0.21)	(0.77)	NA
<b>FY18E</b>	(x.xx)	(x.xx)	(x.xx)	(0.07)E	(0.54)	NA
<b>FY17A</b>	(x.xx)	(x.xx)	(x.xx)	(x.xx)	(0.09)	NA
<b>FY16A</b>	(x.xx)	(x.xx)	(x.xx)	(x.xx)	(0.11)	NA

Source: Laidlaw & Company estimates

Ticker:	TLSA
Rating:	<b>Buy</b>
Price Target:	<b>\$17.00</b>

#### Trading Data:

Last Price (03/01/2019)	\$5.00
52-Week High (11/21/2018)	\$1217
52-Week Low (03/01/2019)	\$5.00
Market Cap. (MM)	\$126.01
Shares Out. (MM)	68.0

#### Analyst

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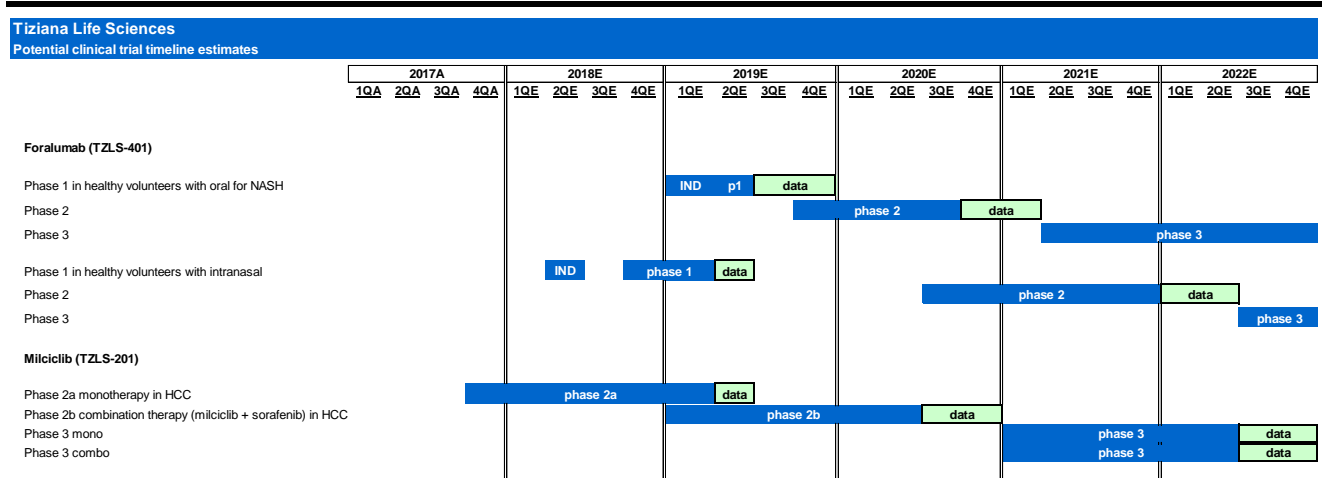
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**Figure 1: Sum-of-the-Parts Analysis**

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Foralumab US royalties	\$166,623	\$11.00
Foralumab EY royalties	\$20,585	\$1.50
Miliciclib WW royalties	\$46,491	\$3.00
Cash (end '19) & tech value	\$22,738	\$1.50
	\$235,852	<b>\$17.00</b>
2019 fully diluted shares out (000)		14,991

Source: Company Reports; Laidlaw and Company estimates

**Figure 2: Potential Clinical Trials Timeline**



Source: Company Reports; Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Tiziana Life Sciences						
Quarterly income statement						
	2017A Year	2018E				2018E Year
		1QA	2QE	3QE	4QE	
(\$000 except per share)						
<b>Revenues</b>						
<b>Total Revenue</b>						
<b>Expenses:</b>						
COGS (% of US Revenue)						
<b>Gross Margin</b>						
G&A	(4,601)	(1,083)	(1,083)	(500)	(500)	(3,166)
R&D	(6,015)	(1,569)	(1,569)	(500)	(500)	(4,138)
<b>Total operating expenses</b>	<b>(10,616)</b>	<b>(2,652)</b>	<b>(2,652)</b>	<b>(1,000)</b>	<b>(1,000)</b>	<b>(7,304)</b>
<b>Operating income</b>						
other income (expense)	(12)					
<b>Loss before income tax</b>	<b>(10,628)</b>	<b>(2,652)</b>	<b>(2,652)</b>	<b>(1,000)</b>	<b>(1,000)</b>	<b>(7,304)</b>
Interest expense						
Provision (benefit) for income tax	1,912					
<b>Net loss</b>	<b>(8,716)</b>	<b>(2,652)</b>	<b>(2,652)</b>	<b>(1,000)</b>	<b>(1,000)</b>	<b>(7,304)</b>
Foreign currency	70					
<b>Adj. NI/(loss)</b>	<b>(8,646)</b>	<b>(2,652)</b>	<b>(2,652)</b>	<b>(1,000)</b>	<b>(1,000)</b>	<b>(7,304)</b>
<b>NI/(loss) as reported</b>						
	<b>(8,646)</b>					
<b>Earning per Share (EPS)</b>						
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$0.09)</b>				<b>(\$0.07)</b>	<b>(\$0.54)</b>
Weighted avg. shares (000)	96,067				13,641	13,641
Fully diluted shares (000)	96,067	-	-	-	13,641	13,641

Source: Company Reports; Laidlaw &amp; Company estimates

Figure 4: Annual Income Statement

<b>Tiziana Life Sciences</b>					
<b>Annual income statement</b>					
(\$000's except per share)	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
<b>Revenues</b>					
<b>Total sales</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
COGS	0	0	0	0	0
<b>Gross margin</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
R&D	(4,007)	(6,015)	(4,138)	(6,500)	(9,500)
G&A	(5,872)	(4,601)	(3,166)	(5,000)	(7,000)
<b>Adj. Net Income</b>	<b>(9,120)</b>	<b>(8,646)</b>	<b>(7,304)</b>	<b>(11,500)</b>	<b>(16,500)</b>
<b>NI/(loss) as reported</b>	<b>(9,770)</b>				
<b>Adj-EPS ex-non-cash</b>	<b>(\$0.11)</b>	<b>(\$0.09)</b>	<b>(\$0.54)</b>	<b>(\$0.77)</b>	<b>(\$0.99)</b>
<b>EPS as reported</b>	<b>(\$0.11)</b>	<b>(\$0.09)</b>			
Shares out (000)	82,909	96,067	13,641	14,991	16,724
Fully diluted shares (000)	82,909	96,067	13,641	14,991	16,724

Source: Company Reports; Laidlaw &amp; Company estimates

## Major Risks

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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.

## DISCLOSURES:

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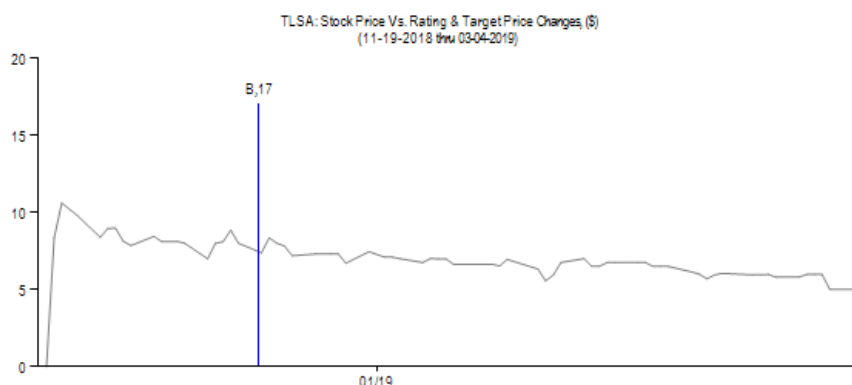
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### RATINGS INFORMATION

#### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
12/17/2018	Buy (B )	7.38

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
12/17/2018	17.00	7.38

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	63.93%	24.59%	3.28%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.92%	1.64%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Gilead Sciences (GILD – Not Rated)  
 Genfit (GNFT – Not Rated)  
 ICPT (Intercept Pharmaceuticals – Buy, \$135 PT)  
 Allergan (AGN – Not Rated)  
 Cirius Therapeutics (CSTX – Not Rated)  
 Novo Nordisk (NVO – Not Rated)

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