July 23, 2019

# Tiziana Life Sciences (TLSA - \$7.60)

Milciclib Reports Impressive Safety in Phase 2a, Efficacy Data Around the Corner.

TLSA recently reported the first part of their Phase 2a trial with Milciclib monotherapy in Sorafenib-refractory or intolerant patients with unresectable or metastatic Hepatocellular Carcinoma (HCC). The primary endpoint of the trial was overall safety. We were encouraged that treatment was well-tolerated and no drug-related deaths were observed. The most frequent yet manageable AEs were diarrhea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash. Although TLSA didn't report their secondary endpoint of efficacy, we expect these data to be reported in 3019 (September). The delay in reporting efficacy results from TLSA's use of an Independent Central Review to conduct both the modified Response Evaluation Criteria in Solid Tumors (mRECIST) guideline and the conventional RECIST1.1 criteria, which we view as a rational step to avoid to the common issue of subjectivity between PIs. As a reminder, this Phase 2a was six month duration (n=31). As most of Sorafenib-refractory patients have < 6 months chances of survival, we saw as positive that 9 out of 14 patients that completed the six month study, asked to continue treatment under compassionate use (four received Milciclib for a total of 9, 11, 13, and 16 months; other five are continuing treatment at 8th, 9th, 9th, 9th, and 11th month). This willingness for compassionate usage is encouraging since other treatments have recently been approved and, while no efficacy data has yet been reported, we believe the lack of deaths is quite encouraging. In terms of Foralumab (fully human anti-CD3 mAb), we want to highlight a few recent findings. Firstly, third party research showed orally administered anti-CD3 resulted in anti-inflammatory gene expression with clean safety up to a dose of 1mg of OKT3 in UC, which again shows the potential of orally delivered mAbs. Secondly, an independent third party article in NEJM reported IV treatment with a humanized anti-CD3 mAb showed delays in progression of T1D, which could grow Foralumab's therapeutic potential. We are reiterating our Buy rating and \$17PT.

- Milciclib shows encouraging safety, secondary efficacy endpoint remains a 3Q19 event. With a clean safety profile, we believe compassionate use and lack of deaths bodes well for upcoming efficacy readout in 3Q19.
- Nasal Foralumab data around the corner amidst positive recent research. As humanized IV anti-CD3 and oral OKT3 show promising results, we continue to view Foralumab as the main reason to own the stock.
- **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

Healthcare / Biotechnology

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

#### **Trading Data:**

Last Price (07/22/2019)	\$7.60
52-Week High (11/21/2018)	\$12.17
52-Week Low (04/01/2019)	\$5.00
Market Cap. (MM)	\$102.4
Shares Out. (MM)	13.7

#### Analyst

Francois Brisebois / Specialty Pharma & Biotech (857) 317-5362 fbrisebois@laidlawltd.com

Source: Laidlaw & Company estimates

FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

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 | 302 4QE | 10E 20E 30E 4QE | 10E 20E

**Figure 2: Potential Clinical Trials Timeline** 

Source: Company Reports; Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Tiziana Life Sciences										
Quarterly income statement										
		004	0.4		00404		2044	\		20405
(\$000	101	201		405	2018A	405	2019		405	2019E
(\$000 except per share)	<u>1QA</u>	2QE	3QE	4QE	<u>Year</u>	<u>1QE</u>	<u> 2QE</u>	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.

## **DISCLOSURES:**

#### ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

#### **EQUITY DISCLOSURES**

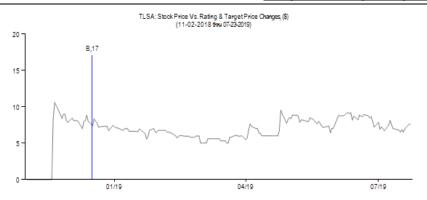
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

#### Additional information available upon request.

Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months.

#### RATINGS INFORMATION

#### **Rating and Price Target Change History**



3 Year Rating Change History						
		Closing Price				
Date	Rating	(\$)				
12/17/2018	Ruy (R.)	7 38				

3 Year Price Change History

Target Closing Price
Price (\$) (\$)

12/17/2018 17.00 7.38

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.	63.64%	22.73%	3.03%	
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.03%	1.52%	0.00%	
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%	

#### ADDITIONAL COMPANIES MENTIONED

### ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices. market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.Laidlawltd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 521 Fifth Ave, 12th Floor, New York, NY 10175 USA.

© 2019 Laidlaw & Co. (UK), Ltd.

NOTES: