Tiziana Life Sciences Plc (TLSA – $0.56*)
Healthcare: Biotech
Buy; $3.00 PT; $57.3M Market Cap
Company Update
Thursday, December 15, 2022

Focused Development of Intranasal Foralumab Within CNS Disorders Continue; FDA Type C Meeting Coming up; Reiterate Buy, $3 PT

Mayank Mamtani
646-885-5463
mmamtani@brileyfin.com

Yuan Zhi, Ph.D.
703-312-1776
yzhi@brileyfin.com

William Wood, Ph.D.
703.312.1748
wwood@brileyfin.com

Sahil Kazmi
703-312-1844
skazmi@brileyfin.com

STOCK DATA	
Market Cap (mil)	$57.3
52-Week Range	$0.53–$1.38
3-Month ADTV	55,730
Shares Outstanding (mil)	102.3
Float (%)	57.0
Short Interest	70,952
Fiscal Year-End	December

FINANCIAL DATA			
FY	2020A	2021A	2022E
EPS	$(0.17)	$(0.24)	$(0.37)
Prior	*$(0.15)*	*$(0.12)*	*$(0.14)*

EPS reported in TILS ordinary shares. TLSA ADS represents 2 ordinary shares

BALANCE SHEET DATA	
	4Q22
Cash & Equivalents	$42.2
Current Assets	$48.7
Total Assets	$48.8
Total Liabilities	$7.5

In $ millions.

Summary and Recommendation

We return to Buy-rated TLSA following the 12/15 release that it has cleared a key pre-clinical safety hurdle heading into its Type C meeting with the FDA, allowing for Ph. II Multiple Sclerosis (MS) study initiation for intranasal foralumab, an anti-CD3 antibody. Recall since foralumab is a fully humanized anti-CD3 antibody that cannot cross-react with CD3 from other species, it has had limited scope of preclinical toxicology studies to evaluate longer-term chronic dosing exposure. Now reporting the successful completion of the *in-vivo* portion of a 13-week GLP safety study in transgenic humanized immunocompetent (HuGEMM) CD3 mouse models, the study has demonstrated that the formulation was well tolerated, up to 50µg per mouse, with no changes in body weight, hematology, or other stress indicators, and no foralumab-related deaths. Indeed, the safety study is a common pre-requisite for an FDA Ph. II meeting for MS candidates and will also support additional CNS studies, e.g., Alzheimer's, planned for intranasal foralumab. The Ph. II meeting with the FDA is expected to occur before year-end, and feedback is expected 1Q23. Additionally, support for MS advancement comes as continued reporting from their open-label expanded access program, where they presented data from the second treated Expanded Access patient (EA2) in the Ph. I study in secondary progressive MS demonstrating continued clinical improvements, including in mobility and in the Expanded Disability Status Scale (EDSS). The data follows a previous update that demonstrated a reduction in PET signal that pointed towards an inhibition of microglial activation across all brain regions (link). Also, in November, the company released data from healthy volunteers showing a positive safety profile and improvements in immune parameters with additional PET data for EA2 is expected by YE22. With TLSA shares trading near 52-week lows, only $15M EV, we highlight a compelling investment opportunity to accumulate additional shares. We reiterate our Buy rating and $3 PT.

Key Points

- **Published data demonstrating that foralumab modulates effector CD8+ T-cell function and induces T-cell regulatory responses in humans.** TLSA announced the publication of data from 27 healthy volunteers in three groups plus one placebo group that assessed safety and immune parameters. Importantly, the data demonstrated no adverse events at any doses of foralumab and/or safety signals at any dose levels and also showed (1) a reduction of CD8+ effector memory cells, (2) an increase in naive CD8+ and CD4+ T cells, and (3) reduced CD8+ T cell granzyme B and perforin expression (Exhibit 1). Overall, a greater immunomodulatory effect was seen with the 50ug dose compared to the 250ug dose, which was consistent with previously conducted animal studies of mucosal tolerance in which higher doses do not induce immune regulation and is likely due to the partial signaling that occurs at intermediate doses, which favors the induction of regulatory cells.
- **Momentum continues for intranasal foralumab in the Ph. I study in SPMS.** Recall in September, TLSA reported updated results from ongoing intranasal foralumab Ph. I study in SPMS from Expanded Access patient 2 (EA2). The data was a follow-up after six months of foralumab treatment totaling 10.5 treatment cycles and demonstrated continued clinical improvements in this patient, including (1) the ability of the patient to walk 100 meters without a cane or need to rest, compared to only three months ago where a cane was required; and (2) a corresponding clinically meaningful improvement in EDSS of 0.5, including a stable pyramidal score, one of eight functional systems (FS) scores that did not worsen over time. Notably, this patient had previously been reported to demonstrate a roughly 10-30% reduction in PET imaging signal, suggesting an inhibition of microglial activation across all brain regions, i.e., cortex, thalamus, white matter, and cerebellum, ***(Continued on pg. 2)***

as well as clinical improvements in a neurological exam and in the timed 25-foot walk test. An additional 6-month follow-up PET imaging scan is expected in 4Q22, which would confirm reduced microglial activation, as well as provide support from the first patient treated. In November, TLSA announced completing the enrollment of the first cohort of four expanded access patients after the FDA permitted the ongoing Expanded Access IND program for intranasal foralumab to enroll up to eight additional patients.

Exhibit 1: Foralumab Modulates Effector CD8+ T-Cell Function and Induces T-Cell Regulatory Responses

		(T1) to T2	(T1) to T3	(T1) to T4
10μg	CD4+ Naive	5.94; p=0.22	1.65; p=0.69	-0.70; p=0.87
	DN LAP+	0.51; p=0.17	0.15; p=0.64	0.13; p=0.67
	CD8+ TEM	-1.99; p=0.07	-0.53; p=0.56	-1.55; p=0.11
	CD8+ GZMB+	-10.45; p=0.09	-6.53; p= 0.21	-8.63; p= 0.11
	CD8+ PRF1+	-5.64; p= 0.04	-1.96; p= 0.36	-5.02; p= 0.04
50μg	CD4+ Naive	**6.01; P=0.04**	**6.49; p=0.03**	2.28; p=0.42
	DN LAP+	-0.03; p=0.85	-0.08; p=0.67	**0.88; p=0.001**
	CD8+ TEM	**-2.71; p=0.004**	**-2.13; p=0.01**	-1.27; p=0.14
	CD8+ GZMB+	**-5.43; p=0.02**	**-4.85; p= 0.03**	**-5.17; p=0.03**
	CD8+ PRF1+	-1.22; p= 0.08	**-1.50; p= 0.04**	-1.38; p= 0.07
250μg	CD4+ Naive	-1.52; p=0.040	1.14; p=0.56	0.89; p=0.65
	DN LAP+	0.17; p=0.32	-0.16; p=0.38	0.36; p=0.06
	CD8+ TEM	0.03; p=0.96	0.08 p=0.90	-1.06; p=0.11
	CD8+ GZMB+	0.74; p= 0.60	-0.51; p= 0.74	-2.07; p= 0.19
	CD8+ PRF1+	-0.15; p= 0.79	-0.81; p= 0.20	-0.22; p= 0.72
Placebo	CD4 Naive	-1.35; p=0.36	1.09 p=0.42	-1.18; p=0.40
	DN LAP+	-0.19; p=0.50	0.49; p=0.06	0.12; p=0.64
	CD8+ TEM	0.16; p=0.85	-0.74; p=0.33	0.02; p=0.98
	CD8+ GZMB+	-9.78; p= 0.05	-4.32; p= 0.34	-3.38; p= 0.48
	CD8+ PRF1+	-5.18; p=0.12	-2.18; p= 0.49	-0.16; p= 0.96

Foralumab reduces CD8+ effector memory cells, increases naive CD8+ and CD4+ T cells, and reduces CD8+ T cell granzyme B and perforin expression

Source: Chitnes et al., Front. Immunol. 2022

Valuation

We base our Buy rating and 12-month price target of $3 per share on a discounted cash flow (DCF) analysis of revenue and cash flow projection through 2030. Our projections of free cash flow to the firm from sales of oral foralumab for moderate to severe Crohn's disease and nasal foralumab for non-active SPMS are adjusted and weighted based on historical regulatory approval rates of similar treatments at similar stages of development. Our DCF analysis applies a WACC-calculated 14.5% discount rate and a 2% terminal growth rate, in line with other clinical-stage biotech companies, yielding an implied enterprise value of $57M. For 2030, the final projected year of our model, we forecast $123M in total risk-adjusted revenue, which assumes a 35% probability of clinical and regulatory success for oral foralumab and 25% for nasal foralumab. Of note, nasal foralumab could potentially pursue approval via orphan drug designation, in our opinion, intended for rare diseases or conditions that affect less than 200,000 individuals in the U.S. Through this regulatory pathway, TLSA will be able to have the agency involved in the early stages regarding the trial design and endpoint selection and likely facilitate expedited approval, given the unmet need. We currently do not ascribe any value in our model to TZLS-501 and milciclib, as we await additional clinical data and subsequent guidance on the regulatory path to market.

Risks

Clinical risks. It is uncertain whether the clinical benefit observed in the clinical studies for foralumab and future registrational trials will be sufficient to support regulatory approval in the U.S., Europe, and other countries. Negative safety and/or efficacy findings in these trials could lead to downward revisions to our price target.

Regulatory risks. The regulatory pathway for all of TLSA's programs in the U.S. is uncertain, and it is unclear whether positive data will be sufficient for a New Drug Application (NDA) submission for each program in the U.S. Additionally, there is no certainty that any of TLSA's drugs will be approved or reimbursed. If the regulatory path for TLSA's candidates is more complex and/or time-consuming than anticipated, there could be a materially negative impact to our estimates and price target, even with success in achieving clinical endpoints.

IP risks. The patent protection related to foralumab and other candidates may expire in the near term and be subject to litigations from competitors. For example, the methods of use patent, pertaining to autoimmune or Inflammatory disease and disorder, for foralumab is expected to expire in 2025.

Commercialization risks. The market potential of TLSA's therapies may not be as significant as projected. In addition, TLSA will need to establish a sales and medical affairs infrastructure in the U.S., Europe, and other geographies for foralumab and other pipeline candidates.

Financing risk. With approximately $42M in cash and cash equivalents, TLSA will likely need to raise additional capital for continued clinical and preclinical candidate development, perhaps via additional equity financing, before reaching profitability, likely resulting in equity share dilution.

Stock price volatility. Share price volatility is common for developmental biopharma firms like Tiziana Life Sciences.

TIZIANA LIFE SCIENCES PLC (TLSA)

Income Statement

$ in millions, except EPS	2017A	2018A	2019A	2020A	2021A	2022E	2023E	2024E	2025E
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Collaboration and license revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cost of sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Research and development	(6.0)	(5.5)	(3.7)	(6.0)	(13.2)	(19.8)	(31.7)	(50.7)	(86.2)
Sales, general and administrative	(4.5)	(4.4)	(6.2)	(11.2)	(13.3)	(16.0)	(20.8)	(27.0)	(32.4)
Operating income (loss)	(10.5)	(9.9)	(9.9)	(28.0)	(27.4)	(35.8)	(52.5)	(77.7)	(118.6)
Interest income (expenses)	0.0	0.0	0.0	(0.3)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Other income (loss)	(0.0)	(0.0)	(0.1)	0.0	0.9	0.9	1.0	1.0	1.1
Net income before income taxes	(10.5)	(9.9)	(10.0)	(28.3)	(26.7)	(35.0)	(51.7)	(76.9)	(117.7)
Provision for income taxes	1.9	1.9	0.7	2.2	3.2	0.0	0.0	0.0	0.0
Net income from continuing operations	(8.6)	(7.9)	(9.3)	(26.1)	(23.4)	(35.0)	(51.7)	(76.9)	(117.7)
Currency translation	0.0	0.0	(0.0)	3.5	(4.5)	0.0	0.0	0.0	0.0
Net income (loss) to common stockholders	(8.6)	(7.9)	(9.3)	(22.7)	(23.4)	(35.0)	(51.7)	(76.9)	(117.7)
Basic EPS attributable to common stockholders	(0.1)	(0.1)	(0.07)	(0.17)	(0.24)	(0.37)	(0.32)	(0.30)	(0.35)
Diluted EPS attributable to common stockholders	(0.1)	(0.1)	(0.07)	(0.17)	(0.24)	(0.37)	(0.32)	(0.30)	(0.35)
Shares, basic (million)	106.4	127.6	136.5	136.5	97.9	94.2	159.9	255.7	339.7
Shares, diluted (million)	106.4	127.6	136.5	136.5	97.9	94.2	159.9	255.7	339.7

Cash Flow Statement

$ in millions	2017A	2018A	2019A	2020A	2021A	2022E	2023E	2024E	2025E
Net change in cash and cash equivalents	(6.0)	5.5	(5.1)	63.9	(21.7)	(34.0)	8.5	20.5	(20.4)
Cash and cash equivalents at beginning of period	5.8	0.1	5.3	0.2	65.8	42.2	8.2	16.7	37.3
Cash and cash equivalents at end of period	0.1	5.3	0.2	65.8	42.2	8.2	16.7	37.3	16.9
CASH FLOWS FROM OPERATING ACTIVITIES									
Consolidated net loss before income taxes	(10.5)	(9.9)	(10.0)	(28.3)	(26.7)	(35.0)	(51.7)	(76.9)	(117.7)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:									
Convertible loan interest accrued	0.0	0.0	0.1	0.3	0.2	0.0	0.0	0.0	0.0
Convertible loan interest paid as equity	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Shares issued in lieu of fees	0.0	0.1	0.1	0.5	0.0	0.0	0.0	0.0	0.0
Share based payment – options	0.5	0.7	1.3	5.1	5.2	5.0	5.0	5.0	5.0
Cancellation of options	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Share based payment – warrants	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Bonus to be settled in equity	0.0	0.0	0.0	13.5	0.9	0.0	0.0	0.0	0.0
Net (increase) in related party receivables	0.0	0.0	(0.3)	(0.0)	(0.1)	0.0	0.0	0.0	0.0
Net increase in related party payables	0.0	0.1	0.4	1.1	(0.7)	0.0	0.0	0.0	0.0
Net (increase)/decrease in operating assets/other receivables	0.1	(0.2)	0.2	(0.4)	0.5	0.5	0.6	0.6	0.7
Net increase/(decrease) in operating liabilities /other liabilities	2.3	2.0	(0.0)	(1.0)	(0.5)	(0.5)	(0.6)	(0.6)	(0.7)
Depreciation and amortization	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Loss on foreign exchange	0.0	(0.3)	0.2	0.2	(1.9)	(2.0)	(2.1)	(2.3)	(2.4)
Lease adjustment	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Depreciation of right-of-use asset	0.0	0.0	0.2	0.1	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Loss on disposal of right of use asset	0.0	0.0	0.1	0.0	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Increase in taxation receivable	0.0	2.8	1.0	0.0	1.4	1.5	1.6	1.7	1.8
Impairment of SharDNA SPA	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0
Gain from disposal of intellectual property	0.0	0.0	0.0	(2.7)	0.0	0.0	0.0	0.0	0.0
Net cash provided by/(used in) operating activities	**(7.5)**	**(4.6)**	**(6.8)**	**(11.3)**	**(21.8)**	**(30.6)**	**(47.3)**	**(72.5)**	**(113.4)**
CASH FLOWS FROM INVESTING ACTIVITIES									
Purchases of equipment	(0.0)	0.0	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Acquisition of other investments	0.0	0.0	0.0	(0.1)	0.2	0.0	0.0	0.0	0.0
Net cash provided by/(used in) investing activities	**(0.0)**	**0.0**	**(0.0)**	**(0.1)**	**0.1**	**0.0**	**0.0**	**0.0**	**0.0**
CASH FLOWS FROM FINANCING ACTIVITIES									
Proceeds from sale of common stock, net	1.5	9.9	0.0	71.2	0.0	-3.2	60.0	100.0	100.0
Proceeds from issuance of convertible loan notes	0.0	0.0	1.9	0.2	0.0	0.0	0.0	0.0	0.0
Proceeds from debt financing	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of warrants and options	0.0	1.5	0.0	4.3	0.1	0.0	0.0	0.0	0.0
Proceeds from the exercise of warrants and options	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Repayment of leasing liabilities	0.0	0.0	(0.2)	(0.3)	(0.2)	0.0	0.0	0.0	0.0
Financing costs paid	0.0	(1.3)	0.0	0.0	0.0	(0.2)	(4.2)	(7.0)	-7.0
Net cash provided by/(used in) financing activities	**1.5**	**10.1**	**1.7**	**75.3**	**(0.0)**	**-3.4**	**55.8**	**93.0**	**93.0**
Exchange difference	**0.0**	**0.0**	**0.0**	**1.7**	**(2.0)**	**0**	**0**	**0**	**0**

TIZIANA LIFE SCIENCES PLC (TLSA)
DCF analysis

Mayank Mamtani
+1 (646) 885-5463
mmamtani@brileyfin.com

Fiscal year	2018A	2019A	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	Terminal value
Fiscal year end date	*12/31/18*	*12/31/19*	*12/31/20*	*12/31/21*	*12/31/22*	*12/31/23*	*12/31/24*	*12/31/25*	*12/31/26*	*12/31/27*	*12/31/28*	*12/31/29*	*12/31/30*	
Revenues	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 84.60	$ 168.04	$ 265.78	$ 379.62	$ 502.95	
Cost of product sales	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ (12.69)	$ (25.21)	$ (39.87)	$ (56.94)	$ (75.44)	
Gross Profit	-	-	-	-	-	-	-	-	71.9	142.8	225.9	322.7	427.5	
R&D expense	(5.5)	(3.7)	(6.0)	(13.2)	(19.8)	(31.7)	(50.7)	(86.2)	(107.8)	(129.3)	(135.8)	(129.0)	(122.6)	
SG&A expense	(4.4)	(6.2)	(11.2)	(13.3)	(16.0)	(20.8)	(27.0)	(32.4)	(48.6)	(63.2)	(82.1)	(98.5)	(118.2)	
Total operating expenses	(9.9)	(9.9)	(17.2)	(26.5)	(35.8)	(52.5)	(77.7)	(118.6)	(156.4)	(192.5)	(217.9)	(227.6)	(240.8)	
Operating income (EBIT)	**(9.9)**	**(9.9)**	**(17.2)**	**(26.5)**	**(35.8)**	**(52.5)**	**(77.7)**	**(118.6)**	**(84.5)**	**(49.7)**	**8.0**	**95.1**	**186.7**	
Taxes	-		2.2	3.2	-	-	-	-	-	-	1.7	18.3	35.7	
After tax operating income	(9.9)	(9.9)	(19.4)	(29.8)	(35.8)	(52.5)	(77.7)	(118.6)	(84.5)	(49.7)	6.3	76.8	151.0	
(+) depreciation and amortization	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
(-) capital expenditures	0.0	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	(4.7)	(9.2)	(14.6)	(20.9)	(27.7)	
(-) change in working capital	1.8	0.1	(1.4)	0.0	0.0	0.0	0.0	0.0	(20.0)	(21.2)	(22.5)	(23.8)	0.0	
(+) deferred taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
(+) other non-cash items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Unlevered free cash flow	(8.1)	(9.8)	(20.8)	(29.8)	(35.8)	(52.5)	(77.7)	(118.6)	(109.1)	(80.1)	(30.8)	32.2	123.4	
Time period (years)			-	-	-	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	
Discount factor					1.0	0.9	0.8	0.7	0.6	0.5	0.4	0.4	0.34	
PV				-	(35.78)	(45.81)	(59.27)	(79.01)	(63.48)	(40.70)	(13.67)	12.46	41.76	
													PV of Term	340.73

EV	57.2
+ Cash and Cash equivalents	42.2
Company value	99.4
- Long-term debt	0.0
Equity value	$99
Fully diluted ADS shares outstanding	58.6
Price/share	**$ 3.00**
WACC	14.5%
Terminal growth rate	2%

Shares (20-F, May 23, 2022)				**Dilution**
0,000 shares, on exercise of convertible notes	0.000	shares	$0.00 WAEP	0.000
22,234,000 shares, on exercise of stock options	22.234	shares	$0.00 WAEP	22.234
697,000 shares, on exercise of warrants	0.697	shares	$0.00 WAEP	0.697
0,000 shares, on exercise of unvested RSUs	0.000	shares	$0.00 WAEP	0.000
Possible dilution (million shares)				**22.931**

Assumptions	
Date	12/13/2022
Fiscal year ending (1-12)	12
Fiscal year ending (month)	December
Projections discounted to (1-12)	12.00
Projections discounted to (month)	December
Shares outstanding	94.177

WACC Calculations	
Risk-free rate	3.0%
Adjusted beta	1.64
Rm-Rf	7.0%
Re	14.5%
Rd	0.0%
WACC, calculated	14.5%

Balance Sheet	
Total debt	0.00
Cash and equivalents	42.19
Net debt	(42.19)
Debt, as a % of equity	0.00%
Cash per share	$ 0.45
Closing price, 12-13-22	$ 0.56
MC ($M), 12-13-22	$ 32.8

*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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Rating	B. Riley Securities, Inc. Research Distribution [1]	B. Riley Securities, Inc. Banking Services in the past 12 months[1]
BUY [Buy]	77.32%	45.94%
HOLD [Neutral]	22.68%	34.94%
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(1) As of midnight on the business day immediately prior to the date of this publication.

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