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Tiziana Life Sciences Plc (TLSA – $0.78*)

Healthcare: Biotech
Buy; $3.00 PT; $79.3M Market Cap
Company Update
Friday, May 5, 2023

Value Play Exploiting Differentiated but Highly De-risked Anti-CD3 Innovation Within MS and Additional Immunology Indications; Reiterate Buy, $3 PT

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STOCK DATA	
Market Cap (mil)	$79.3
52-Week Range	$0.50–$1.39
3-Month ADTV	146,144
Shares Outstanding (mil)	102.3
Float (%)	57.0
Short Interest	104,337
Fiscal Year-End	December

FINANCIAL DATA			
FY	2021A	2022A	2023E
EPS	$(0.24)	$(0.15)	$(0.15)
Prior	-	*$(0.37)*	-

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

BALANCE SHEET DATA	
	4Q23
Cash & Equivalents	$18.1
Current Assets	$24.3
Total Assets	$26.5
Total Liabilities	$6.9

In $ millions.

Summary and Recommendation

We return to our Buy-rated Tiziana (TLSA—Buy, $30 PT) thesis primarily focused on mid-stage Non-Active Secondary Progressive Multiple Sclerosis (SPMS) study execution for its anti-CD3 fully human mAb, foralumab, where TLSA anticipates releasing additional data from Expanded Access patients 3-6 (EA3-EA6) in SPMS in 2Q23 and complete Ph. II SPMS protocol submission in 3Q. We are particularly encouraged by recent foralumab-related data releases, (1) AD/PD'23 Dr. Howard Weiner's presentation focused on the reduction of microglia activation and improved behavior in an Alzheimer's disease (AD) mouse model; (2) publication in the journal, Proceedings of the National Academy of Sciences (PNAS) noting the compelling immunological basis for intranasal foralumab's mechanism of action; and (3) at the American Academy of Neurology 2023 (AAN'23) with a podium presentation by Dr. Saef Izzy titled, "Modulating CNS neuroinflammation in animal models of intracerebral hemorrhage by nasal anti-CD3". On the latter, Dr. Izzy presented preclinical work demonstrating that nasal anti-CD3 increased FoxP3+ Tregs (FoxP3, a known repressor of activation) and IL-10-producing FoxP3+ Tregs in the brain, alongside reducing microglial activation and lesion volume; which collectively also resulted in improved behavior outcomes. This has now guided TLSA to advance foralumab into human testing for hemorrhagic stroke. Additional pipeline-related activities include (1) IND filing on the heels of $3M of non-dilutive grant funding secured for a Ph. IIa trial in AD, and (2) initiate type 1 diabetes-focused program, particularly relevant post Sanofi's recent PRVB acquisition ($2.9B; $250%+ premium) where foralumab could be viewed as a "differentiated fast-follower" to humanized anti-CD3 infusion therapy in FDA-approved TZIELD. We commend management's much-needed pipeline pruning efforts to extend cash runway, also reflected in recent stock outperformance YTD, i.e., +34% vs. 3% for XBI, but note additional balance sheet bolstering could allow for increased focus on foralumab-focused early to mid-stage development that could be accompanied by a regular cadence of clinical data-related catalysts.

Key Points

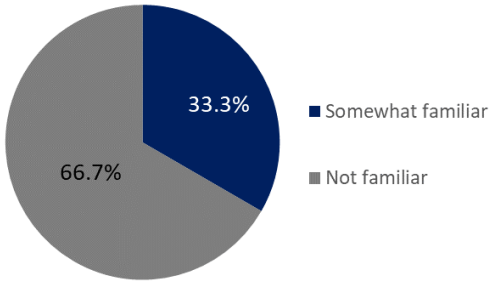
- **Steadily advancing MS program towards Ph. II initiation, supported by a slew of expanded access program (EAP) data.** Now having received the go-ahead to initiate Ph. II trial in patients with Non-Active Secondary SPMS) following a type C meeting with the FDA, TLSA is expected to submit a Ph. II protocol to the FDA this month and is expected to begin the trial in 3Q23. Recall, prior data from patients EA1 and EA2 have been particularly impressive, with EA1 demonstrating impressive whole-brain foralumab treatment effects at three and six months of treatment, e.g., standardized uptake value ratio (SUVR) data of -23% and -38%, respectively, when compared to a pseudo reference region that showed minimal change in PET SUV across time points. Additional data from EA2 continued the trend and was able to walk 100 meters without a cane, and demonstrating an improving EDSS score from 6.0 to 5.5 following eight months of treatment despite worsening from 3.5 in 2018 to 6.0 in 2021 despite ocrelizumab therapy. By 11 months, EA2 was further reported walking 200 meters with no cane, and EDSS falling further from 5.5 to 5.0, with pyramidal score remaining stable. EA2 noted a full point of improvement, something not typically seen in MS patients. Based on EA1 and EA2, TLSA expanded to 10 patients, i.e., eight more enrolled. We expect to see data updates surrounding patients EA3-EA6 in 2Q23, following three months of dosing, which completed in March, as well as additional long-term biomarker data for EA1 and EA2, following with additional PET imaging for EA3-EA6 by ~1 month. When coupled with our recent MS prescriber survey involving familiarity with anti-CD3 therapeutic approach, ***Continued on page 2...***

we continue to view foralumab as an important novel therapeutic in the MS landscape (Exhibit 1, 2); notably mediating the T cell neuroinflammation component, which we anticipate the upcoming EA patient data reporting as further improving.

- **PNAS publication highlights several overlapping pathways making the case for pursuing additional inflammatory conditions.** TLSA's recent publication in PNAS titled, "Nasal administration of anti-CD3 mAb (Foralumab) downregulates NKG7 and increases TGFB1 and GIMAP7 expression in T cells in subjects with COVID-19" helps to illustrate the growing overlap in mechanism of action (MOA) for their fully humanized intranasal anti-CD3 (link). Of note, the paper highlights the immunological basis of foralumab's MOA is based on increasing production of naive-like T cells and Tregs, while concomitantly decreasing effector T cell production and suppressing effector features in multiple T cell subsets. Specifically, the authors found that the effector function genes NKG7, IL32, GZMA, PRF1, CST7, GZMH, and CCL5 were among the most downregulated genes in treated patients based on differential expression in CD3+ T cells. Additional upregulation of TGFB1 expression in treated patients was found to be present in effector cells but not naïve or Treg cells suggesting that foralumab acted to restrain T cell effector function rather than inducing Treg cells in the periphery. In summary, foralumab is seen as (1) restraining effector features in CD3+ T cells, (2) inducing naive-like cells, and (3) inducing the secretion of tissue remolding factors. Importantly, mRNA expression changes seen here were also seen in patients with progressive multiple sclerosis (MS) and treated with foralumab. These changes included decreased NKG7 and GIMAP7, as well as increased TGFB1 mRNA expression. Now based on these data, including foralumab's established role in deactivating microglia, TLSA plans to advance intranasal foralumab for the treatment of long COVID, commencing a Ph. IIa placebo controlled trial following positive feedback from the FDA. More importantly, this also bodes well for TLSA going forward with their upcoming Alzheimer's disease IND filing, which further down the road could be an interesting candidate used on top of monoclonal Ab's addressing amyloid/tau.
- **FY22 EPS of ($0.15) came ahead of our estimates of ($0.37).** R&D and SG&A of $13.0M and $1.6M came in below our estimates of $19.8M and $16.0M. TLSA ended FY22 with cash and cash equivalents of $18.1M on hand, with no debt. Additionally, we updated model to remove Crohn's disease related risk-adjusted revenues and near-term R&D spend; implying cash runway estimated to 2H24/early 2025.

Exhibit 1. How familiar are you with anti-CD3 therapy approach, e.g., intranasal Foralumab to treat SPMS?

EU



Source: Guidepoint Survey and B. Riley Securities Research

Exhibit 2. How important a contributor is T cell mediated neuroinflammation to treating MS?

EU

Source: Guidepoint Survey and B. Riley Securities Research

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 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 $63M. For 2030, the final projected year of our model, we forecast $173M in total risk-adjusted revenue, which assumes a 25% probability of clinical and regulatory success for nasal foralumab. 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 $18M 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	2022A	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)	(13.0)	(16.8)	(25.3)	(35.4)
Sales, general and administrative	(4.5)	(4.4)	(6.2)	(11.2)	(13.3)	(1.6)	(7.4)	(8.9)	(11.6)
Operating income (loss)	(10.5)	(9.9)	(9.9)	(28.0)	(27.4)	(14.6)	(24.3)	(34.2)	(47.0)
Interest income (expenses)	0.0	0.0	0.0	(0.3)	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)
Other income (loss)	(0.0)	(0.0)	(0.1)	0.0	0.9	(0.8)	(0.8)	(0.9)	(0.9)
Net income before income taxes	(10.5)	(9.9)	(10.0)	(28.3)	(26.7)	(15.4)	(25.1)	(35.1)	(47.9)
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)	(26.131)	(23.4)	(15.4)	(25.1)	(35.1)	(47.9)
Currency translation	0.0	0.0	(0.0)	3.5	(4.5)	(3.6)	0.0	0.0	0.0
Net income (loss) to common stockholders	(8.6)	(7.9)	(9.3)	(26.1)	(23.4)	(15.4)	(25.1)	(35.1)	(47.9)
Basic EPS attributable to common stockholders	(0.1)	(0.1)	(0.07)	(0.27)	(0.24)	(0.15)	(0.15)	(0.13)	(0.14)
Diluted EPS attributable to common stockholders	(0.1)	(0.1)	(0.07)	(0.27)	(0.24)	(0.15)	(0.15)	(0.13)	(0.14)
Shares, basic (million)	106.4	127.6	136.5	97.3	97.9	101.5	167.3	263.1	347.1
Shares, diluted (million)	106.4	127.6	136.5	97.3	97.9	101.5	167.3	263.1	347.1

Cash Flow Statement

$ in millions	2017A	2018A	2019A	2020A	2021A	2022A	2023E	2024E	2025E
Net change in cash and cash equivalents	(6.0)	5.5	(5.1)	63.9	(21.7)	(23.7)	34.4	61.6	48.7
Cash and cash equivalents at beginning of period	5.8	0.1	5.3	0.2	65.8	42.2	18.1	52.5	114.1
Cash and cash equivalents at end of period	0.1	5.3	0.2	65.8	42.2	18.1	52.5	114.1	162.8
CASH FLOWS FROM OPERATING ACTIVITIES									
Consolidated net loss before income taxes	(10.5)	(9.9)	(10.0)	(28.3)	(26.7)	(15.4)	(25.1)	(35.1)	(47.9)
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	1.8	5.0	5.0	5.0
Cancellation of options	(0.1)	0.0	0.0	0.0	0.0	(3.2)	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
Fair value loss on investment	0.0	0.0	0.0	0.0	0.0	0.9	0.0	0.0	0.0
Loss on disposal of right of use asset	0.0	0.0	0.1	0.0	(0.0)	0.1	0.1	0.1	0.2
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)	(1.2)	0.0	0.0	0.0
Net increase in related party payables	0.0	0.1	0.4	1.1	(0.7)	(1.4)	0.0	0.0	0.0
Net (increase)/decrease in operating assets/other receivables	0.1	(0.2)	0.2	(0.4)	0.5	1.0	1.1	1.1	1.2
Net increase/(decrease) in operating liabilities /other liabilities	2.3	2.0	(0.0)	(1.0)	(0.5)	0.3	0.4	0.4	0.4
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)	(3.2)	(3.4)	(3.6)	(3.8)
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)	0.1	0.1	0.1	0.1
Increase in taxation receivable	0.0	2.8	1.0	0.0	1.4	0.5	0.5	0.6	0.6
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)**	**(19.6)**	**(21.4)**	**(31.4)**	**(44.3)**
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	(4.0)	0.0	0.0	0.0
Net cash provided by/(used in) investing activities	**(0.0)**	**0.0**	**(0.0)**	**(0.1)**	**0.1**	**(4.0)**	**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	0.0	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)	(0.1)	0.0	0.0	0.0
Financing costs paid	0.0	(1.3)	0.0	0.0	0.0	0.0	(4.2)	(7.0)	-7.0
Net cash provided by/(used in) financing activities	**1.5**	**10.1**	**1.7**	**75.3**	**(0.0)**	**(0.1)**	**55.8**	**93.0**	**93.0**
Exchange difference	**0.0**	**0.0**	**0.0**	**1.7**	**(2.0)**	**(0.4)**	**0**	**0**	**0**

TIZIANA LIFE SCIENCES PLC (TLSA)
DCF analysis

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Fiscal year	2018A	2019A	2020A	2021A	2022A	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*	*12/30/30*	
Revenues	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 33.11	$ 66.65	$ 112.80	$ 148.65	$ 173.55	
Cost of product sales	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ (4.97)	$ (10.00)	$ (16.92)	$ (22.30)	$ (26.03)	
Gross Profit	-	-	-	-	-	-	-	-	28.1	56.7	95.9	126.4	147.5	
R&D expense	(5.5)	(3.7)	(6.0)	(13.2)	(13.0)	(16.8)	(25.3)	(35.4)	(42.4)	(46.7)	(49.0)	(46.6)	(44.2)	
SG&A expense	(4.4)	(6.2)	(11.2)	(13.3)	(1.6)	(7.4)	(8.9)	(11.6)	(15.1)	(18.1)	(19.9)	(20.9)	(22.0)	
Total operating expenses	(9.9)	(9.9)	(17.2)	(26.5)	(14.6)	(24.3)	(34.2)	(47.0)	(57.5)	(64.8)	(69.0)	(67.5)	(66.2)	
Operating income (EBIT)	**(9.9)**	**(9.9)**	**(17.2)**	**(26.5)**	**(14.6)**	**(24.3)**	**(34.2)**	**(47.0)**	**(29.4)**	**(8.2)**	**26.9**	**58.9**	**81.3**	
Taxes	-		2.2	3.2	-	-	-	-	-	-	4.9	11.0	15.2	
After tax operating income	(9.9)	(9.9)	(19.4)	(29.8)	(14.6)	(24.3)	(34.2)	(47.0)	(29.4)	(8.2)	22.0	47.9	66.1	
(+) 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	(1.8)	(3.7)	(6.2)	(8.2)	(9.5)	
(-) change in working capital	1.8	0.1	(1.4)	0.0	1.3	1.4	1.5	1.6	(18.4)	(19.5)	(20.7)	(21.9)	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)	(13.2)	(22.9)	(32.7)	(45.4)	(49.6)	(31.3)	(4.9)	17.8	56.5	
Time period (years)						0.75	1.75	2.75	3.75	4.75	5.75	6.75	7.75	
Discount factor						0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.35	
PV						(20.65)	(25.80)	(31.29)	(29.88)	(16.47)	(2.23)	7.15	19.82	
												PV of Terminal Value		162.00

EV	62.6
+ Cash and Cash equivalents	18.1
Company value	80.8
- Long-term debt	0.0
Equity value	$81
Fully diluted ADS shares outstanding	59.1
Price/share	**$ 3.00**
WACC	14.5%
Terminal growth rate	2%

Shares (20-F, April 26, 2023)				**Dilution**
0,000 shares, on exercise of convertible notes	0.000	shares	$0.00 WAEP	0.000
15,324,000 shares, on exercise of stock options	15.324	shares	$0.00 WAEP	15.324
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)				**16.021**

Assumptions	
Date	4.26.23
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	102.273

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	18.12
Net debt	(18.12)
Debt, as a % of equity	0.00%
Cash per share	$ 0.18
Closing price, 4.26.23	$ 0.87
MC ($M), 4.26.23	$ 51.5

*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]	79.63%	42.52%
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SELL [Sell]	0.00%	0.00%

(1) As of midnight on the business day immediately prior to the date of this publication.

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