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Tiziana Life Sciences Plc (TLSA – $2.36*)

Healthcare: Biotech
Buy; $8.00 PT; $229.6M Market Cap
Company Update
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FY20 Recap: Incremental Validation for Nasal Foralumab Bodes Favorably Ahead of Initiating Multiple Trials Throughout CY21; Reiterate Buy, $8 PT

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

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

STOCK DATA	
Market Cap (mil)	$229.6
52-Week Range	$1.76–$12.17
3-Month ADTV	389,310
Shares Outstanding (mil)	97.3
Dividend Yield	0.00%
Short Interest	147,777
Fiscal Year-End	December

FINANCIAL DATA			
FY	2019A	2020A	2021E
EPS	$(0.10)	$(0.15)	$(0.12)
Prior	-	*$(0.05)*	*$(0.08)*

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

BALANCE SHEET DATA	
	4Q21
Cash & Equivalents	$65.8
Current Assets	$70.2
Total Assets	$70.6
Total Liabilities	$8.3

In $ millions.

Summary and Recommendation

We reiterate our Buy rating in follow-up to TLSA's recent FY20 financial results and pipeline updates, including for foralumab which is being developed for both oral and intranasal administration, in the form of (1) incremental data demonstrating the benign safety profile as well as immunomodulatory and anti-inflammatory properties of nasal foralumab, i.e., no apparent symptoms of severe toxicity or cytokine release syndrome; (2) a recently completed trial in mild to moderate C-19 disease, in which nasal foralumab demonstrated a reduction in systemic inflammation as evidenced on both markers of inflammation, IL-6 and C-reactive protein, as well as an improvement of pulmonary inflammation as measured by CT scans and notable recovery in disease-specific symptoms, e.g., smell and taste of treated patients; and (3) disclosed clearance of an Individual Patient Expanded Access IND for a Progressive Multiple Sclerosis study in which an SPMS patient received a nasally administered antibody for the first time as part of a recently initiated trial in 2Q. Recall, as the only fully human anti-CD3 monoclonal antibody candidate in clinical development, TLSA's foralumab, may enable a shorter treatment duration and reduced immunogenicity while also minimizing risks of safety liabilities associated with intravenously delivered therapeutics. Foralumab could also be combined with in-house molecules, including TZLS-501, the company's anti-IL-6R candidate, potentially enabling expansion into additional therapeutic areas, e.g., liver and autoimmune diseases. Near-term, we are particularly encouraged by the nasal foralumab opportunity in MS and continue to like the risk-reward setup into Ph. II readouts in next 2-3 quarters as well as the Ph. II Crohn's study evaluating oral foralumab, ultimately eclipsing PRVB's teplizumab opportunity set, in our view; further upside potential to our model could come from generating additional de-risking data for pan-CDK program, milciclib in oncology.

Key Points

- **Totality of data positions nasal and oral foralumab as a disruptive competitor in difficult to treat autoimmune diseases** with a much more favorable safety profile relative to intravenous therapeutics. TLSA announced recently dosing the first ever SPMS patient with 50mcg nasal foralumab, which will be administered in 3-week cycles, with 3x/week dosing for the first 2 weeks, followed by a 1 week rest period, for a total of 6-months in the Ph. I/II trial. The study will evaluate the impact of foralumab on microglial activation by PET and immunological and neurodegenerative markers; and TLSA will aim to build on compelling data generated in healthy subjects and C-19 patients, i.e., no drug-related safety issues at doses up to 250mcg and significant reduction of lung inflammation, IL-6 and CRP, respectively, also at a higher 100mcg dose for ten consecutive days. Separately, TLSA also reported statistically significant reductions in CD8 cytotoxic T cells, suppressed production of pro-inflammatory cytokine IFN-γ, and stimulation of IL-10 in a single-site, placebo-controlled, dose-ranging study with nasally administered foralumab at 10, 50 and 250 mcg per day, consecutively for 5 days. Importantly, the data also represent incremental validation for nasal administration as an effective, targeted delivery method enabling a differentiated approach to treat patients with neurodegenerative diseases, e.g., SPMS, ALS, and AD. In parallel, TLSA anticipates initiating a Ph. II trial in Crohn's disease patients in 3Q21, having reported no drug-related safety issues even at the highest dose of 5 mg in a prior Ph. I program.
- **FY20 EPS of $(0.15) came below our estimate of $(0.05).** TLSA reported higher operating expenses in FY20 relative to the previous year, largely comprising R&D/G&A expenses of $6.0M/$11.2M attributed to driving forward clinical-stage programs, relative to our projections of $2.0M/6.1M *(continued on pg. 2)*

Separately, TLSA reported the realization of bonus costs of $13.2M that became payable upon meeting a key corporate objective of meaningfully strengthening balance sheet in 2020. TLSA ended FY20 with $66M in cash on hand, sufficient to fund operations through late 2022.

Valuation

We base our Buy rating and 12-month price target of $8 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 13.5% discount rate and a 2% terminal growth rate, in line with other clinical-stage biotech companies, yielding an implied enterprise value of $365M. For 2030, the final projected year of our model, we forecast $770M 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 $66M 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	1H20A	2H20A	2020A	1H21E	2H21E	2021E	2022E	2023E	2024E	2025E
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.6	43.7
Product revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.6	43.7
Collaboration and license revenue	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
Cost of sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(3.1)	(6.5)
Gross profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	17.5	37.1
Research and development	(6.0)	(5.5)	(3.7)	(1.0)	(5.0)	(6.0)	(5.0)	(5.0)	(10.0)	(30.0)	(60.0)	(90.0)	(121.5)
Sales, general and administrative	(4.5)	(4.4)	(6.2)	(4.1)	(7.1)	(11.2)	(7.1)	(7.5)	(14.6)	(18.2)	(24.6)	(29.5)	(35.4)
Other operating expense	0.0	0.0	0.0	0.0	(10.8)	(10.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating income (loss)	(10.5)	(9.9)	(9.9)	(5.1)	(22.9)	(28.0)	(12.1)	(12.5)	(24.6)	(48.2)	(84.6)	(102.0)	(119.8)
Interest income (expenses)	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 income (loss)	(0.0)	(0.0)	(0.1)	0.0	(0.3)	(0.3)	0.0	(0.3)	(0.3)	(0.3)	(0.3)	(0.4)	(0.4)
Net income before income taxes	(10.5)	(9.9)	(10.0)	(5.1)	(23.2)	(28.3)	(12.1)	(12.8)	(24.9)	(48.5)	(84.9)	(102.4)	(120.2)
Provision for income taxes	1.9	1.9	0.7	0.0	2.2	2.2	0.0	0.0	0.0	0.0	0.0	(10.2)	(18.0)
Net income from continuing operations	(8.6)	(7.9)	(9.3)	(5.1)	(21.0)	(26.1)	(12.1)	(12.8)	(24.9)	(48.5)	(84.9)	(92.2)	(102.1)
Currency translation	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss) to common stockholders	(8.6)	(7.9)	(9.3)	(5.1)	(20.8)	(25.9)	(12.1)	(12.8)	(24.9)	(48.5)	(84.9)	(92.2)	(102.1)
Basic EPS attributable to common stockholders	(0.1)	(0.1)	(0.1)	(0.03)	(0.11)	(0.15)	(0.06)	(0.06)	(0.12)	(0.19)	(0.30)	(0.28)	(0.31)
Diluted EPS attributable to common stockholders	(0.1)	(0.1)	(0.1)	(0.03)	(0.11)	(0.15)	(0.06)	(0.06)	(0.12)	(0.19)	(0.30)	(0.28)	(0.31)
Shares, basic (million)	106.4	127.6	136.5	150.2	194.6	169.1	195.1	213.4	204.3	252.4	287.0	332.5	333.3
Shares, diluted (million)	106.4	127.6	136.5	150.2	194.6	169.1	195.1	213.4	204.3	252.4	287.0	332.5	333.3

Cash Flow Statement

$ in millions	2017A	2018A	2019A	1H20A	2H20A	2020A	1H21E	2H21E	2021E	2022E	2023E	2024E	2025E
Net change in cash and cash equivalents	(6.0)	5.5	(5.1)	9.5	56.1	65.6	(9.1)	38.1	29.0	48.2	11.8	49.9	-101.0
Cash and cash equivalents at beginning of period	5.8	0.1	5.3	0.2	9.7	0.2	65.8	65.8	65.8	94.7	143.0	154.8	204.6
Cash and cash equivalents at end of period	0.1	5.3	0.2	9.7	65.8	65.8	56.7	103.8	94.7	143.0	154.8	204.6	103.6
CASH FLOWS FROM OPERATING ACTIVITIES													
Consolidated net loss before income taxes	(10.5)	(9.9)	(10.0)	(5.1)	(21.0)	(26.1)	(12.1)	(12.8)	(24.9)	(48.5)	(84.9)	(92.2)	(102.1)
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	(0.0)	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Convertible loan interest paid as equity	0.0	0.0	0.0	(0.3)	0.3	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	0.0	0.5	0.5	0.5	0.5	1.0	0.0	0.0	0.0	0.0
Share based payment – options	0.5	0.7	1.3	1.3	3.8	5.1	2.5	2.5	5.0	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	0.0	0.0	0.0	0.0
Share based payment – warrants	0.2	0.1	0.0	0.4	(0.4)	0.0	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	0.0	13.5	13.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net (increase) in related party receivables	0.0	0.0	(0.3)	0	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net increase in related party payables	0.0	0.1	0.4	0	1.1	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net (increase)/decrease in operating assets/other receivables	0.1	(0.2)	0.2	(2.5)	2.1	(0.4)	0.0	(0.5)	(0.5)	(0.5)	(0.5)	(0.6)	(0.6)
Net increase/(decrease) in operating liabilities /other liabilities	2.3	2.0	(0.0)	(0.6)	(0.4)	(1.0)	0.0	(1.0)	(1.0)	(1.1)	(1.2)	(1.2)	(1.3)
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
Loss on foreign exchange	0.0	(0.3)	0.2	(0.1)	0.4	0.2	0.0	0.3	0.3	0.3	0.3	0.3	0.3
Lease adjustment	(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
Depreciation of right-of-use asset	0.0	0.0	0.2	0.0	0.1	0.1	0.0	0.1	0.1	0.1	0.1	0.1	0.1
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	0.0	0.0	0.0	0.0
Increase in taxation receivable	0.0	2.8	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Impairment of SharDNA SPA	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gain from disposal of intellectual property	0.0	0.0	0.0	0.0	(2.7)	(2.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash provided by/(used in) operating activities	**(7.5)**	**(4.6)**	**(6.8)**	**(6.6)**	**(2.5)**	**(9.1)**	**(9.1)**	**(10.9)**	**(20.0)**	**(44.8)**	**(81.2)**	**(88.5)**	**(98.6)**
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	0.0	0.0	(1.1)	(2.4)
Acquisition of other investments	0.0	0.0	0.0	0.0	(0.1)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash provided by/(used in) investing activities	**(0.0)**	**0.0**	**(0.0)**	**0.00**	**(0.1)**	**(0.1)**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**(1.1)**	**(2.4)**
CASH FLOWS FROM FINANCING ACTIVITIES													
Proceeds from sale of common stock, net	1.5	9.9	0.0	14.50	56.7	71.2	0.0	50.0	50.0	100.0	100.0	150.0	0.0
Proceeds from issuance of convertible loan notes	0.0	0.0	1.9	0.00	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from debt financing	0.0	0.0	0.0	0.00	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	2.70	1.6	4.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from the exercise of warrants and options	0.0	0	0.0	0.00	0.0	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)	0.00	0.3	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financing costs paid	0.0	(1.3)	0.0	(1.1)	0.0	(1.1)	0.0	(1.0)	(1.0)	(7.0)	(7.0)	(10.5)	0.0
Net cash provided by/(used in) financing activities	**1.5**	**10.1**	**1.7**	**16.1**	**58.7**	**74.8**	**0.0**	**49.0**	**49.0**	**93.0**	**93.0**	**139.5**	**0.0**

TIZIANA LIFE SCIENCES PLC (TLSA)
DCF analysis

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

Fiscal year	2018A	2019A	2020A	2021E	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	$ -	$ -	$ -	$ -	$ -	$ -	$ 20.56	$ 43.66	$ 140.29	$ 253.46	$ 386.51	$ 568.27	$ 770.09	
Cost of product sales	$ -	$ -	$ -	$ -	$ -	$ -	$ (3.08)	$ (6.55)	$ (21.04)	$ (38.02)	$ (57.98)	$ (85.24)	$ (115.51)	
Gross Profit	-	-	-	-	-	-	17.5	37.1	119.2	215.4	328.5	483.0	654.6	
R&D expense	(5.5)	(3.7)	(6.0)	(10.0)	(30.0)	(60.0)	(90.0)	(121.5)	(151.9)	(174.7)	(183.4)	(174.2)	(165.5)	
SG&A expense	(4.4)	(6.2)	(11.2)	(14.6)	(18.2)	(24.6)	(29.5)	(35.4)	(53.1)	(74.3)	(104.0)	(124.8)	(149.8)	
Total operating expenses	(9.9)	(9.9)	(17.2)	(24.6)	(48.2)	(84.6)	(119.5)	(156.9)	(204.9)	(249.0)	(287.4)	(299.0)	(315.3)	
Operating income (EBIT)	**(9.9)**	**(9.9)**	**(17.2)**	**(24.6)**	**(48.2)**	**(84.6)**	**(102.0)**	**(119.8)**	**(85.7)**	**(33.5)**	**41.1**	**184.0**	**339.3**	
Taxes	-		2.2	-	-	-	(10.2)	(18.0)	(16.4)	(6.5)	7.7	34.9	64.4	
After tax operating income	(9.9)	(9.9)	(19.4)	(24.6)	(48.2)	(84.6)	(91.8)	(101.7)	(69.3)	(27.1)	33.4	149.1	274.9	
(+) 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	(1.1)	(2.4)	(7.7)	(13.9)	(21.3)	(31.3)	(42.4)	
(-) change in working capital	1.8	0.1	(1.4)	(1.5)	(1.6)	(1.7)	(1.8)	(1.9)	(21.9)	(23.2)	(24.6)	(26.1)	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)	(26.0)	(49.8)	(86.2)	(94.7)	(106.0)	(98.9)	(64.2)	(12.4)	91.8	232.6	
Time period (years)			0.40	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	
Discount factor			1.0	0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.3	0.28	
PV				(22.95)	(38.64)	(58.98)	(57.05)	(56.29)	(46.28)	(26.46)	(4.52)	29.37	65.55	
													PV of Term	581.42

EV	365.2
+ Cash and Cash equivalents	65.8
Company value	431.0
- Long-term debt	0.0
Equity value	$431
Fully diluted ADS shares outstanding	104.8
Price/share	**$ 8.00**
WACC	13.5%
Terminal growth rate	2%

Shares (20-F, May 17, 2021)				**Dilution**
0,000 shares, on exercise of convertible notes	0.000	shares	$0.00 WAEP	0.000
14,279,000 shares, on exercise of stock options	14.279	shares	$0.00 WAEP	14.279
700,000 shares, on exercise of warrants	0.700	shares	$0.00 WAEP	0.700
0,000 shares, on exercise of unvested RSUs	0.000	shares	$0.00 WAEP	0.000
Possible dilution (million shares)				**14.979**

Assumptions	
Date	5/25/2021
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	194.612

WACC Calculations	
Risk-free rate	2.0%
Adjusted beta	1.64
Rm-Rf	7.0%
Re	13.5%
Rd	0.0%
WACC, calculated	13.5%

Balance Sheet	
Total debt	0.00
Cash and equivalents	65.78
Net debt	(65.78)
Debt, as a % of equity	0.00%
Cash per share	$ 0.34
Closing price, 05-25-21	$ 2.40
MC ($M), 05-25-21	$ 251.5

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

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BUY [Buy]	83.08%	40.12%
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(1) As of midnight on the business day immediately prior to the date of this publication.

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