Zacks Small-Cap Research
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Tiziana Life Sciences PLC (TLSA - NASDAQ)

SPMS Update; Second Patient Gains Access

Based on our DCF model and a 15% discount rate, Tiziana is valued at approximately $7.50 per ADR share. Our model applies a 15% probability of ultimate approval and commercialization for the portfolio of assets including foralumab and milciclib. The model includes contributions from the United States and global developed markets.

Current Price (1/10/22)	$0.94
Valuation	**$7.50**

OUTLOOK

Tiziana is a research and development company advancing a portfolio of candidates for autoimmune disease, cancer and COVID. The lead candidate, foralumab, is a fully human anti-CD3 antibody, being investigated in multiple sclerosis (MS), Crohn's disease (CD) and COVID, administered intranasally and orally via enteric coated capsules. Foralumab is also being used in allogeneic CAR T as a lymphodepletion agent in partnership with Precision BioSciences.

Milciclib is the second candidate and is being investigated as a combination product in multiple oncology indications. The third candidate, TZLS-501, is an anti-IL-6R receptor antibody expected to be the subject of an IND submitted in 2021. TZLS-501 is being investigated as a treatment for COVID and other pulmonary diseases such as ARDS.

Ph2 foralumab clinical trials for MS and CD are targeted for 2021 & Ph2 combination trials for milciclib in coming quarters. Tiziana employs the use of intranasal, oral and inhaled formulations of mAbs that are able to avoid shortcomings of infused & subcutaneous administration.

Our valuation assumes a 2027 regulatory approval & 2028 commercialization of foralumab for both pMS and CD in conjunction with partners.

SUMMARY DATA

52-Week High	**5.29**
52-Week Low	**0.85**
One-Year Return (%)	**-64.9**
Beta	**-0.02**
Average Daily Volume (sh)	**133,434**
Shares Outstanding (mil)	**97.3**
Market Capitalization ($mil)	**91.5**
Short Interest Ratio (days)	**1.59**
Institutional Ownership (%)	**7.2**
Insider Ownership (%)	**39.5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of GBP)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2021	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2022					0.0 E
2023					0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2020	0.00 A	-0.03 A	0.00 A	-0.09 A	-0.12 A
2021	0.00 A	-0.08 A	0.00 E	-0.06 E	-0.12 E
2022					-0.10 E
2023					-0.11 E

WHAT'S NEW

First Patient Update from Intranasal Foralumab in SPMS, Second Patient Enrolled

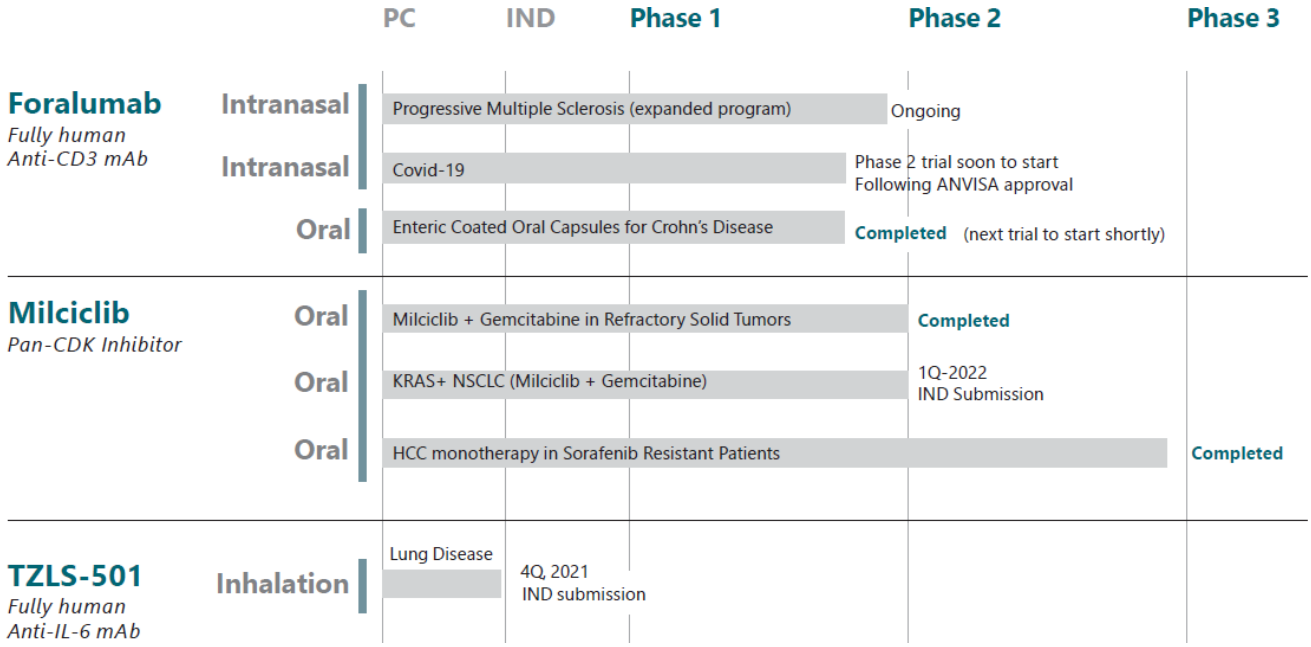
On January 10, 2022, Tiziana Life Sciences (NASDAQ: TLSA) announced a progress update for its first patient in the evaluation of intranasal foralumab in secondary progressive multiple sclerosis (SPMS). The FDA also allowed for continued enrollment based on the favorable data from the first patient, and a second patient has been enrolled under the Individual Patient Expanded Access Program who will be treated at Brigham and Women's Hospital (BWH) at Harvard University.

The first patient enrolled has completed 3 out of 6 months of dosing and the interim data show that intranasal foralumab was well-tolerated, as expected, and demonstrated favorable clinical response. The first patient continues to be treated and their six-month treatment period is expected to be completed by the end of March 2022. Tiziana reported that to date the patient has not shown signs of treatment intolerance or toxicities and appears to be responding well to treatment. The brain imaging data, as analyzed by PET, show reduction in microglial cell activation. In MS patients, destruction of myelin in the central nervous system is associated with activated microglia, a state which is thought to contribute to the disease.[1,2]

Previous studies have shown a positive correlation between increased microglial cell activation and their presence in the brain with cognitive disability, as evidenced by higher scores on the Expanded Disability Status Scale (EDSS). Tysabri (natalizumab) (NASDAQ: BIIB), an approved drug for treatment of MS, is also believed to act via reduction in microglial activation.

The three-month safety data from the first patient were submitted to the FDA to gain approval to treat an additional patient under the Individual Patient Expanded Access Investigational New Drug Application (IND). The FDA responded that a second SPMS patient would be allowed to be dosed with intranasal foralumab. The second patient is already enrolled and treatment is expected to begin in January 2022 with interim clinical data expected in April 2022. The treatment plan will remain the same and investigators will be monitoring safety, neurological, and PET data to evaluate microglial activation. Immunological and neurodegenerative markers will also be monitored.

Exhibit I – Tiziana Pipeline[3]



[1] Lassmann H, Brück W, Lucchinetti CF. The immunopathology of multiple sclerosis: an overview. Brain Pathol. 2007;17(2):210–218.
[2] Prineas JW, Kwon EE, Cho ES, et al. Immunopathology of secondary-progressive multiple sclerosis. Ann Neurol. 2001;50(5):646–657.
[3] Tiziana Corporate Presentation. November 2021

Program Summary

The active SPMS trial is being conducted to determine safety and tolerability. Dosing is 50 mg (25 mg each nostril), three times per week for two weeks followed by a one week break. To assess clinical response, PET imaging will be conducted to assess microglial activation. Cognitive behavior and immuno-biomarker analysis will also be conducted. As per the trial protocol, if safety and tolerability are favorable at three months, dosing will resume for another three months and additional patients may be considered. Complete data is expected to be available in 2Q:22.

Summary

Tiziana updated investors on the clinical progress of its first patient in the evaluation of intranasal foralumab in SPMS. Preliminary observations from the first patient show that intranasal foralumab is well-tolerated and the first patient on the drug has demonstrated favorable clinical response. The FDA has allowed for continued enrollment based on this data and a second patient has been enrolled.

As Tiziana updates investors on its SPMS trial, our focus remains on the two Phase II trials in Crohn's Disease and Multiple Sclerosis. These programs drive the majority of the value in our assessment and address unmet needs in important indications. We maintain our target price of $7.50 per share.

PROJECTED FINANCIALS

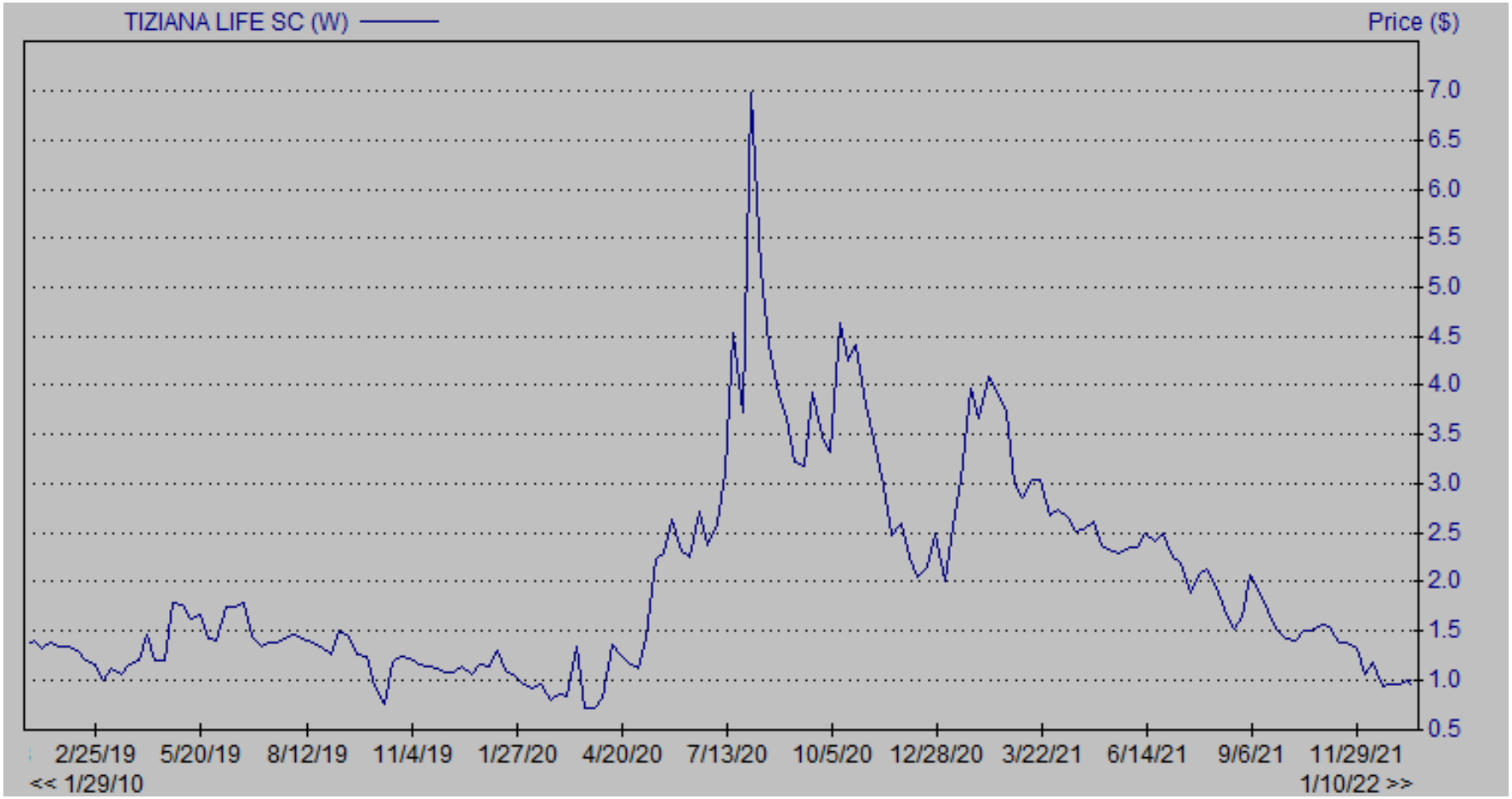
Tiziana Life Sciences PLC - Income Statement

Tiziana Life Sciences Plc	2020 A	1H A	2H E	2021 E	2022 E	2023 E
Total Revenues (£UK)	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**
YOY Growth						
Research & Development	£4,667	£4,355	£11,350	£15,705	£20,801	£21,820
Operating Expenses	£8,724	£8,214	£2,809	£11,023	£5,968	£6,147
Income from operations	-£13,391	-£12,569	-£14,158	-£26,727	-£26,769	-£27,967
Operating Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Other Expense	£8,676	£24	£0	£24	£0	£0
	£0			£0	£0	
Pre-Tax Income	-£22,067	-£12,593	-£14,158	-£26,751	-£26,769	-£27,967
Provision for Income Tax	-£1,719	£0	£0	£0	£0	£0
Tax Rate	7.8%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	**-£20,348**	**-£12,593**	**-£14,158**	**-£26,751**	**-£26,769**	**-£27,967**
Net Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Reported EPS	**-£0.12**	**-£0.084**	**-£0.06**	**-£0.12**	**-£0.10**	**-£0.11**
YOY Growth	124.8%	222.0%	-26.4%	1.0%	-15.3%	3.7%
Basic Shares Outstanding	169,065	150,224	220,000	220,000	260,000	261,970

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Tiziana Life Sciences PLC – Share Price Chart[4]



[4] Source: Zacks Research System

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