

September 21, 2026

Tiziana Life Sciences (TLSA, Buy, \$7 PT)

Last Patient Completes Last Visit in INFORM-MS P2a Trial. Topline Data in October Could Further Establish the TSPO Imaging Biomarker as a Surrogate of Clinical Benefit.

WHAT YOU SHOULD KNOW: Tiziana has produced multiple imaging data sets demonstrating that the anti-CD3 antibody foralumab stimulates regulatory T-Cells (Tregs) and reduces inflammation in the CNS. More specifically, foralumab reduces the numbers of inflammatory cells in relevant regions of patients' brains. This molecular effect seems reasonably likely to translate to clinical benefit across neurodegeneration, but recent surprise readouts in the inflammatory drivers of CV disease (note [HERE](#)) make direct validation of clinical effects of reducing inflammation important. **Broad validation could be a month away.** The biggest near-term catalyst remains the INFORM-MS Phase 2a readout, which just cleared a key operational hurdle as the last patient completed their last visit on 9/21/26. This trial is potentially large enough to begin to show clinical effects that are unlikely to be attributable to disease fluctuation - particularly in this indication where patients generally decline steadily. With database lock expected this week, Tiziana anticipates presenting topline data in October at ACTRIMS/ECTRIMS in Toronto. The 48-patient randomized, double-blind, placebo-controlled trial evaluates two doses of foralumab vs. placebo over 12 weeks, with TSPO PET as the primary endpoint and **fatigue (MFIS) and disability (EDSS) as key secondaries - both should be approvable endpoints.** Although strong signs of clinical benefit are the bigger catalyst, we would view ~75% of patients showing TSPO signal reduction as a positive result. Supporting confidence, all 14 patients in the Expanded Access Program showed stability or improvement within 6 months. Additional data from ongoing MSA and AD trials are expected in 1H27. **Mechanistically very compelling, we believe.** Foralumab is delivered intranasally to NALT lymphoid tissue, where stimulated Tregs interface with the CNS lymphatic system — naturally priming them to reduce inflammation driven by CNS antigens and reprogram the overactive microglial cells central to neurodegenerative disease. As detailed in our recent initiation ([HERE](#)), the company has used TSPO PET imaging to demonstrate foralumab-driven reductions in CNS inflammation across multiple indications, including SPMS, MSA, and AD patients. The SPMS and MSA indications represent meaningful commercial opportunities given significant unmet medical need — approved SPMS drugs are only active early after progression from relapsing-remitting MS, and no disease-modifying therapies currently exist for MSA.

- **The central thesis seems clear, and the approach is relatively simple.** The ability of Tregs to reduce inflammation is as documented as anything in neuroscience and immunology. The ability to stimulate NALT Tregs to fight neurodegeneration has been shown by others and foralumab is certainly easier to deliver than cellular therapies. As a result, the major unknown is whether the Tiziana approach will develop enough Tregs to drive clinical effects. The imaging data seen for SPMS, MSA and AD suggest the approach drives measurable immunomodulation and confidence with the approach should build with the next readouts.
- **Ideal for combinations and mechanistically cleaner.** The nasal delivery and tolerance approaches are both attractive candidates for future combinations as both are distinct from approved therapies for neurodegeneration. Rather than depleting or blocking immune cells, foralumab reprograms the immune system toward tolerance by generating Tregs. Crucially, by stimulating...**Continued on P3.**
- **Valuation:** We value TLSA using a DCF (17.0% discount rate and a 1.0% TG rate).

PLEASE READ: IMPORTANT DISCLOSURES AND ANALYST'S CERTIFICATION APPEAR IN APPENDIX

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Company Data	
Closing Price	\$0.91
Price Target	\$7.00
Market Cap (M)	\$109.13
Shares Out (M)	120.51
Avg Daily Vol-3 Months (M)	0.61

Revisions		
	Previous	Current
Rating	Buy	Buy
Price Target	\$7.00	\$7.00
FY26E EPS	(0.18)	(0.18)
FY27E EPS	(0.18)	(0.18)
FY26E NI	(21.66)	(21.66)
FY27E NI	(22.20)	(22.20)

EPS (GAAP)			
FY Dec	2025A	2026E	2027E
Q1	-	-	-
Q2	(0.05)	(0.08)	(0.08)
Q3	-	-	-
Q4	(0.11)	(0.10)	(0.10)
FY EPS	(0.16)	(0.18)	(0.18)
FY P/E	-	-	-

Net Income			
FY Dec	2025A	2026E	2027E
Q1	-	-	-
Q2	(5.63)	(9.42)	(9.65)
Q3	-	-	-
Q4	(12.80)	(12.24)	(12.55)
FY NI	(18.43)	(21.66)	(22.20)

Source: FactSet, BTIG Estimates and Company Documents reported as \$ currency.
FY = Fiscal Year CY = Calendar Year

Investment Thesis

The foralumab approach seems a straightforward approach to stimulating Treg production, and Tregs are an extremely well-validated modulator of the immune system. As a result, we see the Tiziana programs to be relatively de-risked and the degree and timeline for correction of patients' disease is the big readout. The company is continually generating additional clinical data with readouts in SPMS, MSA and AD all expected in the next 12 months. In each case we expect data sets that corroborate the biomarkers seen to date and continue to support the thesis that true clinical benefit will be seen in larger trials with longer treatment periods.

Upcoming Catalysts

- Topline Phase 2a Data in Non-Active Secondary Progressive Multiple Sclerosis - October 2026
- Multiple System Atrophy (MSA) Phase 2a Readouts - YE2026
- Early Alzheimer's Disease Phase 2 Initial efficacy or biomarker data - 1H27

Base Case Assumptions: \$7 Price Target

Both the SPMS P2a readout and the ongoing cohorts of MSA patients continue to show reductions in CNS inflammation in foralumab-treated patients. Signs of clinical activity are reported from the early trials.

TZLS-401 for SPMS - 50% PoS. 2030 market entry. Peak penetration of 15%. Price of \$70,000 per patient per year with prices increasing 1.5% annually.

TZLS-401 for MSA - 30% PoS. 2031 market entry. Peak penetration of 25%. Price of \$70,000 per patient per year with prices increasing 1.5% annually.

TZLS-401 for AD - 15% PoS. 2032 market entry. Peak penetration of 5%. Price of \$70,000 per patient per year with prices increasing 1.5% annually.

TZLS-401 for ALS - 15% PoS. 2032 market entry. Peak penetration of 15%. Price of \$70,000 per patient per year with prices increasing 1.5% annually.

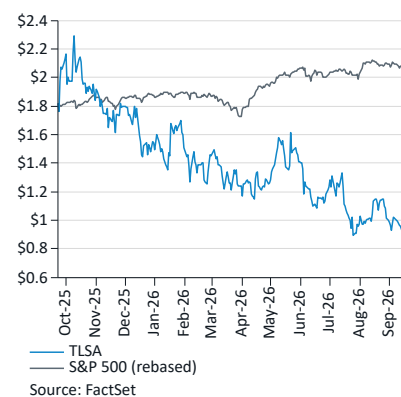
Upside Scenario

Strong signs of clinical activity that correlate with biomarker readouts like TSPO imaging are reported.

Downside Scenario

Biomarker readouts are less robust and only seen in a handful of patients. Any toxicity would be a negative surprise after the company has reported no serious AEs after 37-patient years of exposure to foralumab.

Price Performance



Company Description

Tiziana Life Sciences is a clinical-stage biotechnology company focused on developing therapies for neuroinflammatory and neurodegenerative diseases. The company's lead asset, foralumab — believed to be the only fully human anti-CD3 monoclonal antibody in clinical development — is being evaluated intranasally across multiple indications, including non-active secondary progressive multiple sclerosis (na-SPMS), Alzheimer's Disease, amyotrophic lateral sclerosis (ALS), and Multiple System Atrophy (MSA).

- ...tolerance through the nasal route, foralumab avoids systemic Tcell activation and associated AEs. To date, Tiziana reports no serious AEs in 37 patient years of exposure.
- **Entire pipeline increasingly de-risked by each application.** A reduction of aberrant microglial activity and reductions in Treg activity are seen in each neurodegenerative disease that has been tested. So a simple treatment approach like foralumab could be used in many places. The use of immune modulators in these diseases is an active area of research as evidenced by the high activity around developing NLRP3 inhibitors. Time will tell what the winning approach will be, but using Tregs - an approach with a relatively high antigen specific mechanism - seems to have a very good chance of reducing inflammation without leaving patients open to opportunistic infections.

INCOME STATEMENT



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Tiziana Life Sciences (TLSA) Income Statement

Period Ending \$USD ('000s)	Dec-21 2021A	Dec-22 2022A	Dec-23 2023A	Dec-24 2024A	Jun-25 1H25A	Dec-25 2H25A	Dec-25 2025A	Jun-26 1H26E	Dec-26 2H26E	Dec-26 2026E	Dec-27 2027E
Product Revenue:											
TZLS-401 for SPMS (50% risk adjusted)							-	-	-	-	-
TZLS-401 for MSA (30% risk adjusted)							-	-	-	-	-
TZLS-401 for AD (15% risk adjusted)							-	-	-	-	-
TZLS-401 for ALS (15% risk adjusted)							-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	-	-	-
Operating Expenses:											
Cost of goods sold	-	-	-	-			-	-	-	-	-
Research and development	13,208	12,955	8,113	5,229	3,243	7,036	10,279	3,324	7,212	10,536	10,799
General and administrative	13,311	1,631	9,871	10,565	5,943	4,910	10,853	6,092	5,033	11,124	11,402
Other	855										
Total Operating Expenses	27,374	14,586	17,984	15,794	9,186	11,946	21,132	9,416	12,245	21,660	22,202
Operating Income (Loss) EBIT	(27,374)	(14,586)	(17,984)	(15,794)	(9,186)	(11,946)	(21,132)	(9,416)	(12,245)	(21,660)	(22,202)
Other Income (expense) Net	717	(811)	742	(952)	3,554	(853)	2,701				
Income (Loss) before Taxes	(26,657)	(15,397)	(17,242)	(16,746)	(5,632)	(12,799)	(18,431)	(9,416)	(12,245)	(21,660)	(22,202)
Tax provision	3,240	-	(449)	4,883	0	0	0				
Net Income (Loss)	(23,417)	(15,397)	(17,691)	(11,863)	(5,632)	(12,799)	(18,431)	(9,416)	(12,245)	(21,660)	(22,202)
Foreign currency translation adjustment	(4,478)	(3,582)	1,492	(72)	339	(427)	(88)				
Total comprehensive income (Loss)	(27,895)	(18,979)	(16,199)	(11,935)	(5,293)	(13,226)	(18,519)	(9,416)	(12,245)	(21,660)	(22,202)
Basic EPS, GAAP	(0.24)	(0.15)	(0.17)	(0.11)	(0.05)	(0.11)	(0.16)	(0.08)	(0.10)	(0.18)	(0.18)
Diluted EPS, GAAP	(0.24)	(0.15)	(0.17)	(0.11)	(0.05)	(0.11)	(0.16)	(0.08)	(0.10)	(0.18)	(0.18)
Weighted average shares outstanding, basic	97,932	101,526	102,471	106,672	116,827	119,739	118,283	119,989	120,489	120,239	121,239
Weighted average shares outstanding, diluted	97,932	101,526	102,471	106,672	116,827	119,739	118,283	119,989	120,489	120,239	121,239

Source: BTIG Research estimates

BTIG Covered Companies Mentioned in this Report

Tiziana Life Sciences (TLSA, Buy, \$7 PT; Closing Price: \$0.91)

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Neutral	179	31.7%	Neutral	47	26.3%
Sell	4	0.7%	Sell	0	0.0%

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Company Valuation and Risk Disclosures

Tiziana Life Sciences (TLSA, Buy, \$7 PT)

Valuation: We value TLSA using a DCF (17.0% discount rate and a 1.0% TG rate)

Risks: Tiziana is an established biotech company. It faces all the standard upside and downside risks for that industry, including unexpected outcomes or safety signals from clinical readouts, regulatory uncertainty, and increasingly complex and price-sensitive commercial markets for its product candidates.

Tiziana Life Sciences Rating History as of 09/18/2026



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