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Rating	Buy
Price (10/30/2026)	$0.80
Price Target	$9.00

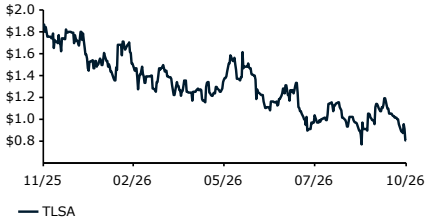
Market Data

% to Target	1,025.0%
52-Week High	1.96
52-Week Low	0.76
Market Cap (mil)	93.5
Cash & Equivalents	$12.0
Total Debt	$0.0
Enterprise Value	$81.5
Cash per Share	$0.10
Shares Outstanding (mil)	116.9
3-Month ADTV	752,091
Short Interest (% of Float)	4.4%
Short interest (mil)	2.8
Float	63.8
Fiscal Year-End	Dec

Estimates

FY	2024A	2025A	2026E
EPS Diluted	(0.11)	(0.16)	(0.16)
Revenue ($M)	0.0	0.0	0.0

Performance Chart



Tiziana Life Sciences Ltd (TLSA)

Foralumab Meets Phase 2a INFORM-MS Primary Endpoints; 50µg Dose Reduces Neuroinflammation in na-SPMS

Tiziana Life Sciences (TLSA; Buy) announced positive topline results from INFORM-MS, its randomized, double-blind, placebo-controlled Phase 2a trial evaluating intranasal foralumab, a fully human anti-CD3 monoclonal antibody, in patients with non-active secondary progressive multiple sclerosis (na-SPMS).

We reiterate our Buy rating with a 12-month Price Target of $9/share.

Foralumab for Neurodegenerative Diseases

Foralumab is a fully human anti-CD3 monoclonal antibody designed to stimulate regulatory T cells through intranasal administration, offering a potential approach to neuroinflammatory and neurodegenerative diseases. In an open-label expanded-access program, all 14 treated na-SPMS patients showed disease stability or improvement within six months, although these observations lacked a placebo control. The candidate is also being evaluated in Phase 2 trials for Alzheimer's disease, amyotrophic lateral sclerosis, and multiple system atrophy. In na-SPMS, microglial activation is believed to contribute to progressive disability despite the absence of recent relapses or new MRI activity, and treatment options remain limited.

Foralumab for Na-SPMS

Na-SPMS is characterized by progressive disability that occurs independently of relapses. No FDA-approved therapies are specifically indicated for this population, leaving substantial unmet needs in managing disability progression and fatigue.

The randomized, double-blind, placebo-controlled trial achieved both primary endpoints. After 12 weeks, intranasal foralumab at 50µg significantly reduced neuroinflammation versus placebo, as measured by decreased microglial activation on $[^{18}F]PBR06$ TSPO PET imaging (p=0.0168). Both the 50µg and 100µg doses were safe and well tolerated.

Study Results

Primary Endpoints: Microglial Activation and Safety

The 50µg intranasal foralumab group met the neuroinflammation endpoint, as measured by TSPO PET imaging. An ANCOVA of participants with evaluable PET scans (n=40), adjusted for baseline white-matter/global-brain standardized uptake value ratio (SUVR), TSPO binding affinity, baseline Expanded Disability Status Scale (EDSS), timed 25-foot walk (T25FW), recruiting center, and scanner-pair category, demonstrated an adjusted treatment difference versus placebo of −0.0231 in globally normalized white-matter SUVR (95% CI: −0.0416 to −0.0046; p=0.0168). Statistical significance was maintained in a model excluding EDSS and T25FW adjustments (p=0.0394).

The reduction in microglial activation was consistent with previously published expanded-access results (Chitnis *et al*., 2026). No statistically significant PET difference was observed over the treatment period in the 100µg group (n=11).

The trial also achieved its primary safety objectives, with both doses well tolerated. All 48 participants completed treatment, with no deaths, discontinuations due to adverse events, or study drug–related serious adverse events. Treatment-emergent adverse events occurred

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in 15 of 18 placebo recipients (83.3%) and 23 of 30 foralumab recipients across both doses (76.7%). Events affecting at least 10% of participants in either foralumab group included headache, falls, nasal congestion, and rhinorrhea.

Secondary Endpoints

Although the study was not powered to demonstrate definitive clinical improvements, fatigue scores improved numerically in both foralumab groups. Mean Modified Fatigue Impact Scale (MFIS) total scores declined by 6.17 points in the 50µg group and 7.18 points in the 100µg group, versus 3.12 points with placebo.

Both treatment groups exceeded the cited four-point threshold for clinically meaningful improvement from baseline, with reductions approximately twice those observed with placebo and consistent with prior expanded-access findings. Within-group improvements from baseline to Week 12 were statistically significant at both 50µg (p=0.035) and 100µg (p=0.040); statistical significance versus placebo was not reported.

Next Steps

Tiziana plans to complete a comprehensive analysis of the INFORM-MS dataset and present detailed findings at an upcoming scientific congress. The company also intends to discuss the results with the FDA to determine the potential development path for intranasal foralumab in na-SPMS.

Company Description for: Tiziana Life Sciences Ltd (TLSA)

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative nasal approach has the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's lead candidate, intranasal foralumab, which is the only fully human anti-CD3 mAb currently in clinical development, has demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

Risks for: Tiziana Life Sciences Ltd (TLSA)

Tiziana Life Sciences is a development-stage company, and investment is subject to risk.

Clinical Trial Risk

The company is progressing on multiple clinical studies for intranasal foralumab. Early data are encouraging and warrant further clinical development. Intranasal foralumab was found to be safe and effective, without any serious adverse events. However, in the ongoing clinical trials, intranasal foralumab may not be deemed safe and effective. So far, interim safety analyses of all clinical trials conducted have not identified any significant safety concerns.

Regulatory Risk

The FDA and European regulators may require additional clinical trials for Intranasal foralumab beyond the ones Tiziana currently anticipates.

Competition Risk

Intranasal foralumab is facing competition from existing approved drugs and other drug candidates for treating MS, AD and ALS.

Financing Risk

The cash position was around $12M (January 2026). We estimate the company to burn approximately $21M over the next 12 months. The company needs to raise additional equity capital to support its clinical development, unless licensing deals are forged for its development-stage assets. Financing may not be available under favorable terms, or at all.

Valuation for: Tiziana Life Sciences Ltd (TLSA)

We arrive at our 12-month price target of $9 per share by assessing the after-tax, risk-adjusted NPV of potential future cash flows from foralumab in non-active SPMS. The probability-adjusted (45%), fully taxed (21%) NPV at a 15% discount rate of potential cash flows until 2043 is approximately $1.2B, equivalent to $9 per share, corresponding to our 12-month price target. Potential factors that could prevent shares from reaching our price target include the failure of foralumab to demonstrate significant efficacy benefits or being deemed unsafe, leading to the discontinuation of clinical programs and commercial launch. In addition, the company may not be able to raise additional funds to complete development.

Appendix

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Rating distribution (as of) November 1, 2026	Investment Banking Relationships
Buy: 74.0%	Buy: 84.0%
Neutral: 16.4%	Neutral: 16.0%
Sell: 0.0%	Sell: 0.0%
Not Rated: 9.6%	Not Rated: 0.0%

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Tiziana Life Sciences Ltd Rating History as of 10/30/2026

