BIOTECHNOLOGY EQUITY RESEARCH

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

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KOL Call Reinforces INFORM-MS Readout: Fatigue Is a Key Symptom. More PET Imaging Details Expected But Topline Seen As Supportive.

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WHAT YOU SHOULD KNOW: Today's KOLs principally reinforced the message from the recent INFORM-MS readout: na-SPMS patients have few options, and the 12-week Phase 2a showed a statistically significant reduction in a ley symptom of the disease - fatigue. Measurements of microglial activation on TSPO PET at 50 µg were seen as the most informational - based on patient size - but both doses showed promising effects as gauged by this imaging modality that is continually being refined and validated. The fatigue (MFIS) improvement was stressed as very striking and somewhat surprising (seen in both doses) in a trial both management and the KOLs called a short study. We still view this as a meaningful step toward validating a key surrogate: successfully targeting inflammation predicts clinical outcomes. The fatigue signal and PET are the only places the drug-effect has separated so far. Longer, larger studies will need to show whether that carries over to disability. **Useful review of the medical need.** Unmet need was the through-line of the call: the speakers said that about 25% of MS patients become progressive and that many are non-active, with no new attacks or MRI lesions. Many of the patients they've treated stayed on ocrelizumab and kept getting worse where they argued that progressive MS is driven by microglial inflammation, which no prior trial has targeted this way. Today's press release adds that no FDA-approved therapy is specifically indicated for na-SPMS or progression independent of relapse activity (PIRA) and that PIRA accounts for roughly 70–90% of confirmed worsening events in treated RRMS. Fatigue was the more remarkable endpoint. The study wasn't powered for clinical endpoints, yet MFIS fell 6.17 points at 50 µg (p=0.035) and 7.18 points at 100 µg (p=0.040), versus 3.12 for placebo. Both foralumab arms exceeded the 4-point clinical threshold. The p-values are against each arm's own baseline, not against placebo, and placebo also improved. The roughly twofold gap versus placebo is what we think makes the signal credible. Speakers said the fatigue benefit was "quite to our surprise" and noted that most drugs take months to show full effect, so seeing it at 3 months was "quite remarkable." No other clinical endpoint has hit yet and EDSS didn't change at 3 months. Management said it didn't expect it in a study this short and pointed to the open-label expanded access (EA) program, which has longer follow-up. In the EA program, all 10 published patients stabilized on EDSS and 3 of 4 treated for 12 months improved. We read the flat EDSS as expected rather than negative. The 100 µg arm (n=11) did not reach significance on PET, which we attribute largely to its small size. Management described the arm as exploratory and said earlier Phase 1 data showed less immunomodulation at higher doses (250 µg). Safety remains clean, and next steps are in view. All 48 patients completed treatment, with no study-drug-related SAEs. Treatment-emergent AEs were numerically lower in the foralumab arms (76.7%) than in placebo (83.3%). The company reports 37.4 patient-years of exposure with no related SAEs and no anti-drug antibodies in EA samples.

- **Does this energize the field?** The fatigue result is the headline surprise. The study was not powered to demonstrate a statistically significant clinical effect — and yet it did. The MFIS Total Score declined by -6.17 points in the 50 µg arm (p=0.035) and -7.18 points in the 100 µg arm (p=0.040), versus only -3.12 in placebo — both exceeding the established 4-point threshold for clinical significance, and both reaching statistical significance versus their own baselines. The approximately twofold greater improvement in both foralumab arms relative ...**Continued on P3**
- **Valuation:** We value TLSA using a DCF (17.0% discount rate and a 1.0% TG rate).

Company Data	
Closing Price	$0.62
Price Target	$7.00
Market Cap (M)	$79.33
Shares Out (M)	127.87
Avg Daily Vol-3 Months (M)	0.78

Revisions	Previous	Current
Rating	Buy	Buy
Price Target	$7.00	$7.00
FY26E EPS	(0.18)	(0.18)
FY27E EPS	(0.19)	(0.19)
FY26E NI	(23.62)	(23.62)
FY27E NI	(24.21)	(24.21)

EPS (GAAP)			
FY Dec	2025A	2026E	2027E
Q1	-	-	-
Q2	(0.05)	(0.10)**A**	(0.09)
Q3	-	-	-
Q4	(0.11)	(0.10)	(0.10)
FY EPS	**(0.16)**	**(0.18)**	**(0.19)**
FY P/E	-	-	-

Net Income			
FY Dec	2025A	2026E	2027E
Q1	-	-	-
Q2	(5.63)	(12.39)**A**	(11.66)
Q3	-	-	-
Q4	(12.80)	(12.24)	(12.55)
FY NI	**(18.43)**	**(23.62)**	**(24.21)**

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

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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

- Multiple System Atrophy (MSA) Phase 2a updates - 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.

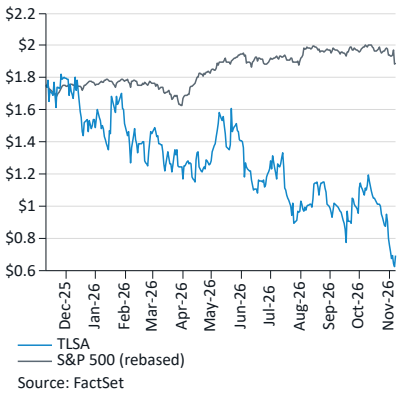
Upside Scenario

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



Source: FactSet

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).

- ...to placebo further reinforces that this is a real signal, not noise. No change was seen in EDSS over the 3-month duration, which is unsurprising — EDSS is a notoriously insensitive measure over short intervals in a slowly progressing disease, and we would not read the flat EDSS as a negative. Next steps include full data analysis, presentation at an upcoming scientific congress, and an FDA engagement to discuss the development path forward in na-SPMS.
- **On safety**, both doses were clean: all 48 participants completed treatment, there were no deaths, no discontinuations due to adverse events, and no study drug-related SAEs — an important confirmation after 37 patient-years of exposure with no serious AEs reported to date. Treatment-emergent adverse events were actually numerically lower in the foralumab arms (76.7% combined) than in placebo (83.3%), with the most common events being headache, fall, nasal congestion, and rhinorrhea.

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 1H26A	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	6,431	7,212	13,643	13,984
General and administrative	13,311	1,631	9,871	10,565	5,943	4,910	10,853	4,943	5,033	9,976	10,225
Other	855										
Total Operating Expenses	**27,374**	**14,586**	**17,984**	**15,794**	**9,186**	**11,946**	**21,132**	**11,374**	**12,245**	**23,619**	**24,209**
Operating Income (Loss) EBIT	**(27,374)**	**(14,586)**	**(17,984)**	**(15,794)**	**(9,186)**	**(11,946)**	**(21,132)**	**(11,374)**	**(12,245)**	**(23,619)**	**(24,209)**
Other Income (expense) Net	717	(811)	742	(952)	3,554	(853)	2,701	(1,013)			
Income (Loss) before Taxes	**(26,657)**	**(15,397)**	**(17,242)**	**(16,746)**	**(5,632)**	**(12,799)**	**(18,431)**	**(12,387)**	**(12,245)**	**(23,619)**	**(24,209)**
Tax provision	3,240	-	**(449)**	4,883	0	0	0	0			
Net Income (Loss)	**(23,417)**	**(15,397)**	**(17,691)**	**(11,863)**	**(5,632)**	**(12,799)**	**(18,431)**	**(12,387)**	**(12,245)**	**(23,619)**	**(24,209)**
Foreign currency translation adjustment	(4,478)	(3,582)	1,492	(72)	339	(427)	(88)	22			
Total comprehensive income (Loss)	**(27,895)**	**(18,979)**	**(16,199)**	**(11,935)**	**(5,293)**	**(13,226)**	**(18,519)**	**(12,365)**	**(12,245)**	**(23,619)**	**(24,209)**
Basic EPS, GAAP	**(0.24)**	**(0.15)**	**(0.17)**	**(0.11)**	**(0.05)**	**(0.11)**	**(0.16)**	**(0.10)**	**(0.10)**	**(0.18)**	**(0.19)**
Diluted EPS, GAAP	**(0.24)**	**(0.15)**	**(0.17)**	**(0.11)**	**(0.05)**	**(0.11)**	**(0.16)**	**(0.10)**	**(0.10)**	**(0.18)**	**(0.19)**
Weighted average shares outstanding, basic	97,932	101,526	102,471	106,672	116,827	119,739	118,283	127,874	128,124	127,999	128,874
Weighted average shares outstanding, diluted	97,932	101,526	102,471	106,672	116,827	119,739	118,283	127,874	128,124	127,999	128,874

Source: BTIG Research estimates

BTIG Covered Companies Mentioned in this Report

Tiziana Life Sciences (TLSA, Buy, $7 PT; Closing Price: $0.62)

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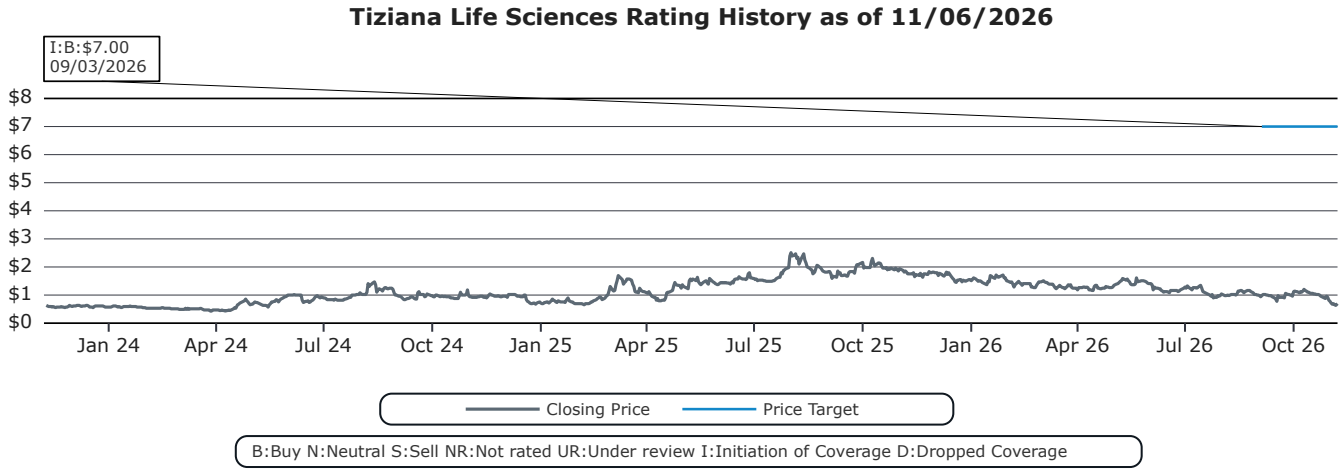
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Tiziana Life Sciences (TLSA, Buy, $7 PT)

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.



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