

OKYO Pharma Limited (OKYO)
Rating: Buy

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FDA Endorses Planned Phase 2b/3 Trial in Neuropathic Corneal Pain; Reiterate Buy

Stock Data		1/28/2026
Price		\$2.19
Exchange		NASDAQ
Price Target		\$7.00
52-Week High		\$3.35
52-Week Low		\$0.90
Enterprise Value (M)		\$78
Market Cap (M)		\$82
Shares Outstanding (M)		37.6
3 Month Avg Volume		186,420
Short Interest (M)		0.16
Balance Sheet Metrics		
Cash (M)		\$4.3
Total Debt (M)		\$0.0
Total Cash/Share		\$0.11
Book Value/Share		\$(0.08)

Cash (M): pro forma

EPS (\$) Diluted			
Full Year - Mar	2024A	2025A	2026E
1Q	--	--	(0.02)
2Q	(0.34)	(0.08)	(0.02)
3Q	--	--	(0.05)
4Q	(0.24)	(0.06)	(0.08)
FY	(0.50)	(0.12)	(0.19)
Revenue (\$M)			
Full Year - Mar	2024A	2025A	2026E
1Q	--	--	0.0
2Q	0.0	0.0	0.0
3Q	--	--	0.0
4Q	0.0	0.0	0.0
FY	0.0	0.0	0.0

OKYO reports semiannually. Our projections are offered quarterly.



FDA confirms Phase 2b/3 trial design; study slated to start in 1H26.

Yesterday, OKYO Pharma announced that it had a successful Type C meeting with the FDA regarding the Phase 2b/3 trial of urcosimod for the treatment of neuropathic corneal pain (NCP). Key highlights from the meeting include (1) FDA confirmed the approach that the proposed primary endpoint of the Visual Analogue Scale (VAS) pain reduction at Week 12 is clinically meaningful, including explicit acknowledgment that a ≥ 2 -point improvement on the VAS scale represents a meaningful treatment effect; (2) FDA provided statistical guidance to enhance robustness; (3) FDA endorsed the proposed study design, sample size (n=120), and powering assumptions, and agreed that the Ocular Pain Assessment Survey (OPAS) is appropriate as supportive quality-of-life evidence; and (4) FDA alignment on the Chemistry, Manufacturing and Controls (CMC) strategy and key clinical elements, with no material issues raised. With the FDA's endorsement, the company is slated to initiate the Phase 2b/3 trial in 1H26. We reiterate our Buy rating and \$7 PT.

Favorable changes in corneal nerve structure observed in the neuropathic corneal pain trial.

In December 2025, OKYO Pharma announced favorable data from new analyses based on corneal images from the Phase 2 trial of urcosimod in neuropathic corneal pain (NCP) (n=18). The analyses showed that patients treated with 0.05% urcosimod demonstrated favorable changes in corneal nerve structure, which were not observed in the placebo group. Specifically, the urcosimod group showed median increases in total nerve fiber count (+2.0, n/0.16 mm², Inter Quartile Range (IQR) 0.54 to 3.63) and total nerve fiber length (+2.6 mm/mm², IQR 1.55 to 5.67; p=0.057 vs. placebo). In comparison, the placebo group showed median decreases in total nerve fiber count (-1.92, n/0.16 mm², IQR -2.79 to -0.04) and total nerve fiber length (-1.63 mm/mm², IQR -3.76 to 0.63). While this is an exploratory endpoint, the consistent and meaningful directional improvements demonstrate the potential of urcosimod to support corneal nerve restoration, in our view. Combined neuropathic corneal pain with previously announced data showing statistically significant reduction in mean pain scores, the improvements in corneal nerve structure suggest that targeting the chemerin receptor pathway could be a viable therapeutic approach for NCP, which has no FDA-approved therapy.



Phase 2 data show statistically significant pain reduction in NCP. In July 2025, the company reported positive proof-of-concept data from a Phase 2 trial of urcosimod for the treatment of NCP. This double-masked, randomized, placebo-controlled study enrolled 18 patients at a single site and 17 patients have completed the study. Subjects were randomized in a 1:1:1 ratio to receive treatment with 0.05% urcosimod, or 0.1% urcosimod, or placebo four times daily for 12 weeks. The primary endpoint is change in mean pain scores from baseline (Visit 1, Day 0) to end of treatment (Visit 4, Day 84) as measured by a VAS score (on 0-10 scale where 0 is no pain and 10 is worst pain imaginable). Results showed that the 0.05% urcosimod group had a statistically significant reduction in mean pain scores of 5.5 ($p=0.025$), while the placebo group had a reduction in mean pain scores of 2.75 ($p=0.035$), thus demonstrating a delta of 2.75 between urcosimod and placebo following the 12-week treatment period. Of note, all the patients in the 0.05% urcosimod group had moderate to severe NCP pain scores, while 75% of placebo group patients had only mild NCP pain scores at baseline, indicating a worse baseline condition for the 0.05% urcosimod group. In addition, 67% of patients in the 0.05% urcosimod group demonstrated greater than 50% improvement in pain compared to 33% in the placebo group, and 0.05% urcosimod showed a marked reduction in pain scores as early as Week 4.

Valuation and Risks. Our 12-month price target is derived from an estimated market value of the firm at \$300M. This includes a discounted cash flow (DCF) analysis-based asset value of \$300M for urcosimod (formerly OK-101), using a 15% discount rate and 1% terminal growth rate, and conservatively excludes the cash position. Assigned probability of approval is 15% for DED and 20% for NCP. Assuming 43M shares outstanding at the end of September 2026, this yields a value of approximately \$7 per share. Risks include, but are not limited to: (1) failure of urcosimod in clinical trials; (2) failure of urcosimod to secure regulatory approval in the U.S.; (3) failure of urcosimod to achieve commercial success due to market size, penetration rate, and/or competition; and (4) dilution risk.

Table 1: OKYO Pharma Limited (OKYO)—Historical Income Statements, Financial Projections

FY end March 31

\$ in thousands, except per share data

	2023A	2024A	2025A		2026E					2026E	
			1HA	2HA	2025A	1Q	2Q	3Q	4Q		
Revenue											
Product revenue	-	-				-					-
Other revenue	-	-				-					-
Total revenue	-	-	-	-	-	-	-	-	-	-	-
Expenses											
Cost of sales	-	-	-	-	-	-	-	-	-	-	-
Research and development	6,338	8,244	2,216	38	2,254	50	50	1,000	2,000	3,100	
General and administrative	6,850	7,506	1,123	3,714	4,838	800	800	1,200	1,500	4,300	
Total expenses	13,187	15,750	-	3,339	-	3,753	7,092	850	850	2,200	3,500
Gain (loss) from operations	(13,187)	(15,750)	-	(3,339)	-	(3,753)	(7,092)	(850)	(850)	(2,200)	(3,500)
Other income/expense											
Finance costs	(97)	(1,053)	(758)	(120)	(878)						
Finance income	-	-									
Total investment income and other	(97)	(1,053)	-	(758)	-	(120)	(878)	-	-	-	-
Loss before provision for income taxes	(13,284)	(16,803)	-	(4,098)	-	(3,872)	(7,970)	(850)	(850)	(2,200)	(3,500)
Provision for income taxes	12	(22)	1,418	1,846	3,264						
Net income (loss)	(13,272)	(16,825)	-	(2,680)	-	(2,026)	(4,706)	(850)	(850)	(2,200)	(3,500)
Net loss per share (basic)	(0.60)	(0.50)	(0.08)	(0.06)	(0.12)	(0.02)	(0.02)	(0.02)	(0.05)	(0.08)	(0.19)
Net loss per share (diluted)	(0.60)	(0.50)	(0.08)	(0.06)	(0.12)	(0.02)	(0.02)	(0.02)	(0.05)	(0.08)	(0.19)
Weighted average number of shares outstanding (basic)	22,257	33,336	33,573	36,021	39,488	36,816	37,618	40,133	42,648	39,304	
Weighted average number of shares outstanding (diluted)	22,257	33,336	33,573	36,021	39,488	36,816	37,618	40,133	42,648	39,304	

Source: Company reports and H.C. Wainwright & Co. estimates.

Table 2: OKYO Pharma Limited (OKYO)—Historical Balance Sheets, Financial Projections

FY end March 31

\$ in thousands, except per share data

	3/31/2023	3/31/2024	2025A		2026E						
			9/30/2024	3/31/2025	3/31/2025	6/30/2025	9/30/2025	12/31/2025	3/31/2026	3/31/2026	
Assets											
Current assets:											
Cash and cash equivalents	4,045	827	987	1,561	1,561	3,646	2,996	10,296	6,996	6,996	
Related party receivables	-	-	-	-	-	-	-	-	-	-	
Current taxation receivable	559	559	1,483	1,872	1,872	1,872	1,872	1,872	1,872	1,872	
Other receivables	592	152	356	242	242	242	242	242	242	242	
Total current assets	5,197	1,538	-	2,827	-	3,675	3,675	5,761	5,111	12,411	9,111
Property and Equipment, net	7	3	2	2	2	2	2	2	2	2	
Right of use asset	-	-	-	-	-	-	-	-	-	-	
Total Assets	5,204	1,541	-	2,829	-	3,677	3,677	5,763	5,113	12,413	9,113
Liabilities and shareholder equity											
Current liabilities											
Trade and other payables	4,263	7,062	9,607	8,368	8,368	8,368	8,368	8,368	8,368	8,368	
Related party payable	779	359	446	859	859	859	859	859	859	859	
Loan payable to related party	2,215	-	2	-	-	-	-	-	-	-	
Lease liabilities - current	-	-	-	-	-	-	-	-	-	-	
Total current liabilities	7,257	7,421	-	10,054	-	9,227	9,227	9,227	9,227	9,227	
Lease liabilities - non current	-	-	-	-	-	-	-	-	-	-	
Total Liabilities	7,257	7,421	-	10,054	-	9,227	9,227	9,227	9,227	9,227	
Shareholder's equity											
Ordinary share capital	-	-	-	-	-	-	-	-	-	-	
Share premium	131,386	143,113	144,050	146,717	146,717	149,453	149,453	158,753	158,753	158,753	
Accumulated deficit	(125,698)	(142,523)	(145,203)	(143,025)	(143,025)	(143,675)	(144,325)	(146,325)	(149,625)	(149,625)	
Share options reserve	3,629	4,749	5,075	1,185	1,185	1,185	1,185	1,185	1,185	1,185	
Warrants reserve	82	94	94	94	94	94	94	94	94	94	
Shares to be issued (Loan Notes) - Equity	-	-	115	-	-	-	-	-	-	-	
Convertible Loan Note reserve	-	-	435	950	950	950	950	950	950	950	
Foreign currency translation reserve	(11,453)	(11,311)	(11,792)	(11,470)	(11,470)	(11,470)	(11,470)	(11,470)	(11,470)	(11,470)	
Total stockholders' equity	(2,053)	(5,880)	-	(7,226)	-	(5,550)	(5,550)	(3,464)	(4,114)	3,186	(114)
Total liability and shareholder's equity	5,204	1,541	-	2,829	-	3,677	3,677	5,763	5,113	12,413	9,113

Source: Company reports and H.C. Wainwright & Co. estimates.

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Distribution of Ratings Table as of January 27, 2026					
Ratings	Count	Percent	IB Service/Past 12 Months		
			Count	Percent	
Buy	576	87.27%	146	25.35%	
Neutral	59	8.94%	8	13.56%	
Sell	1	0.15%	0	0.00%	
Under Review	24	3.64%	4	16.67%	

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