

OKYO Pharma Ltd. (OKYO)

Overweight

Mgmt Meeting Takeaways: Compelling Risk/Reward Setup; Execution in Focus

CONCLUSION

We hosted a virtual management meeting with OKYO, which provided additional clarity on the regulatory path for urcosimod in neuropathic corneal pain (NCP). FDA alignment on the NEPTUNE Ph3 design, including the 0.05% dose, Week 12 VAS pain endpoint, moderate-to-severe enrollment, and potential for a single pivotal trial, provides meaningful development de-risking. Formal US screening is expected to begin in late Sept / early Oct, with topline data targeted for Dec '27 and cash runway extending through readout. At ~\$80M mkt cap, OKYO's valuation compares favorably with mgmt's preliminary estimate of ~500K potential US NCP patients and a potential price point of ~\$75K per treatment course, although execution, replication of Ph2 data in the larger Ph3 population, and validation of the NCP market remain key focus items.

- **FDA alignment provides important de-risking.** OKYO confirmed that its Type B meeting with the FDA resulted in agreement on the key elements of its Phase 3 program (NEPTUNE), including use of the 0.05% dose of urcosimod, VAS pain reduction at Week 12 as the primary endpoint, a 1-month post-treatment follow-up period, and enrollment of moderate-to-severe NCP patients, defined as a baseline VAS score of ≥ 5 . The FDA also agreed that a 2-point VAS improvement vs placebo would be considered clinically meaningful and potentially sufficient to support approval. Importantly, the FDA indicated that limiting enrollment to moderate-to-severe patients would not restrict the potential label to that subgroup, preserving the opportunity for a broad NCP label. Mgmt believes the moderate-to-severe population should maximize the probability of success, given the greater treatment effect and lower placebo response observed in the Ph2 subgroup, which included n=8 with baseline VAS scores of ≥ 5 . NEPTUNE is powered at 90% with a prespecified p-value threshold of 0.025, while a p-value of <0.001 could support the use of the study as a single pivotal trial. OKYO believes the FDA's willingness to consider a single pivotal study reflects the high unmet need in NCP.
- **NEPTUNE's Ph3 design is intended to maximize statistical power and support the product's value proposition.** The study will enroll 111 patients with moderate-severe NCP randomized 2:1 to urcosimod vs placebo and is powered at 90% with a prespecified p-value threshold of 0.025. OKYO sized the study using a conservative standard deviation assumption of 3-points based on its Ph2, which mgmt believes is a conservative approach that should increase the likelihood of achieving a p-value below 0.001. While mgmt is confident in its ability to meet the FDA-agreed 2-point VAS threshold, based on the approximately 3.5-point pbo-adj improvement observed in the Ph2 moderate-to-severe subgroup, investors remain focused on the potential for this effect to be replicated in the larger Ph3 study. **Continued on Page 2...**

RISKS TO ACHIEVEMENT OF PT & RECOMMENDATION

Risks include clinical, regulatory, commercial, financing and IP.

COMPANY DESCRIPTION

OKYO is developing a first-in-class chemerin receptor agonist for Neuropathic Corneal Pain (NCP).

PRICE: US\$1.56

TARGET: US\$7.00

Our \$7 PT is based on a DCF through 2035E(15% discount rate) and assumes ~\$328Min peak risk-adjusted Uracosimod sales in Neuropathic Corneal Pain, Post Surgery and Dry Eye Disease, in both the US and EU.

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Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$7.00
FY26A Rev (mil)	—	US\$0.0
FY27E Rev (mil)	—	US\$0.0
FY26A EPS	—	US\$(0.24)
FY27E EPS	—	US\$(0.30)
52-Week High / Low	US\$3.20 / US\$1.34	
Shares Out (mil)	37.4	
Market Cap. (mil)	US\$58.3	
Avg Daily Vol (000)	101	
Div Yield	0.00%	
Fiscal Year End	Dec	

Price Performance - 1 Year



Source: Bloomberg

YEAR	REVENUE (US\$ m)					EARNINGS PER SHARE (US\$)				
	Mar	Jun	Sep	Dec	FY	Mar	Jun	Sep	Dec	FY
2025A	0.0	—	0.0	—	0.0	(0.08)	—	(0.05)	—	(0.12)
2026A	0.0	—	0.0	—	0.0	(0.07)	—	(0.17)	—	(0.24)
2027E	0.0	—	0.0	—	0.0	(0.15)	—	(0.15)	—	(0.30)

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<http://www.pipersandler.com/researchdisclosures>.

- **Breakthrough Therapy Designation (BTD) remains a near-term catalyst.** OKYO submitted its BTD application several weeks ago and expects FDA feedback around mid-Oct 2026. Mgmt estimates a >50% probability of receiving the designation, citing NCP's progressive nature, bilateral disease burden, substantial impact on quality of life, high unmet need, and lack of approved therapies. Mgmt believes the BTD case for NCP may compare favorably with the prior precedent for Oxervate in neurotrophic keratitis (NK), which received BTD in 2017, noting that NCP is typically bilateral and highly symptomatic, whereas NK is generally unilateral and is less symptomatic. OKYO also believes the FDA's prior willingness to authorize compassionate use for urcosimod supports the view that the agency recognizes the severity of the disease and the positive benefit-risk profile of the therapy. Mgmt acknowledged that the primary limitation to receiving BTD is the relatively limited clinical experience to date.
- **Enrollment preparations appear well advanced.** Formal screening in the US is expected to kick off in late Sept / early Oct '26, with the first 2 sites expected to be operational during that period. Sites are already informally pre-screening patients with at least 3 mos of persistent pain (no improvement or worsening) despite standard treatment, allowing formal screening to begin promptly once sites are activated. NEPTUNE is expected to use a deliberately concentrated network of 13 experienced NCP centers in total, including 8 in the US and 5 in Europe. OKYO has completed CTIS/EMA submission, with final approval of EU site through CTIS expected in late Nov '26 (assuming no major regulatory questions). Mgmt views the limited number of sites as a strategic choice with a focus on centers that have pre-identified patients available for screening. OKYO is also implementing additional screening tools intended to confirm that enrolled patients have true NCP rather than nonspecific ocular pain. OKYO believes this approach should improve enrollment quality and reduce the risk of rushing recruitment or waiting for patients to present. The company is targeting completion of enrollment by approximately Jun '27 and topline data around Dec '27.
- **Ph3 trial includes add'l endpoints that could support the commercial and payer value proposition.** Beyond the primary VAS pain endpoint, the trial also includes exploratory secondary endpoints such as photomicroscopy assessments of corneal nerve anatomy. Mgmt believes that demonstrating improvement in nerve structure within 3 mos could support the disease-modifying nature of urcosimod. This distinction could be important with payers, with mgmt referencing its prior experience with Oxervate, where payers wanted evidence that a treatment could meaningfully alter the disease and potentially reduce the need for chronic treatment.
- **Disease and company awareness remain major priorities.** OKYO is continuing to build awareness of both NCP and the company through upcoming ophthalmology and optometry meetings, including the American Academy of Ophthalmology, the Academy of Optometry, and the European Society of Cataract and Refractive Surgery. Mgmt believes NCP remains significantly underdiagnosed and that the investor community has yet to fully appreciate the potential market opportunity. OKYO estimates the US prevalence of NCP is >200K but <1M, with an internal estimate of ~500K patients. However, the company is conducting additional prevalence and TAM analyses with Verana and Komodo, with results expected toward YE26. Mgmt also believes the severity of NCP and lack of effective therapies could support a premium price point, potentially around \$75K per treatment course (for reference, Oxervate is priced at \$110K).
- **NCP diagnosis is established among specialists but remains underrecognized more broadly.** Investors inquired about how NCP is diagnosed and whether it has a dedicated ICD-10 code. Mgmt noted that NCP does not currently have a specific ICD-10 code, but is recognized as a distinct clinical entity by corneal specialists and regulatory agencies. Diagnosis is based on persistent corneal pain that is disproportionate to ocular surface findings, with physicians using topical anesthetic response to assess whether pain has a

peripheral neuropathic component. Corneal microscopy can provide additional confirmation by identifying abnormal nerve morphology, although mgmt noted that these diagnostic tools are not routinely used outside of specialized corneal centers. OKYO believes broader physician education and adoption of these diagnostic methods will be important to identifying the significant number of currently undiagnosed patients. OKYO is addressing this through increased KOL engagement, ophthalmology and optometry conferences, medical education initiatives, and additional disease-prevalence work.

- **Investors inquired about the lower efficacy observed with the higher 0.1% dose vs the 0.05% dose in Ph2.** Mgmt explained that, at higher concentrations, the lipid anchor can form polyaggregates that conceal the active peptide within the emulsion, resulting in less available drug despite the higher nominal dose. By contrast, OKYO believes the 0.05% formulation does not meaningfully form these aggregates, supported by extensive in vitro and in vivo analyses across different concentrations and temperatures. The company recently filed new IP regarding this aggregation-related mechanism, but has not disclosed the underlying data. OKYO has also completed manufacturing of a commercial-grade lot of the 0.05% formulation, which is ready for use in the Ph3 NEPTUNE study.
- **Cash runway reiterated through topline Ph3 data readout in Dec '27.** OKYO believes its existing cash position is sufficient to fund operations through topline Ph3 data, expected in Dec '27. Mgmt noted that additional capital could potentially be raised in the future to support commercialization and market development, but the company is currently focused on the NEPTUNE program and is not pursuing additional indications before the Ph3 readout.

OKYO P&L (data in \$M except EPS)	2024A	1H25A	2H25A	2025A	1H26A	2H26A	2026A	1H27E	2H27E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Product Revenue - US	-	-	-	-	-	-	-	-	-	-	11.0	22.7	36.1	61.5	100.1	129.3	162.6	210.5
Product Revenue - EU	-	-	-	-	-	-	-	-	-	-	-	-	9.5	19.1	29.3	48.6	77.2	117.7
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	11.0	32.2	55.2	90.8	148.7	206.5	259.4	328.2
COGS	-	-	-	-	-	-	-	-	-	-	1.1	3.0	4.9	7.5	11.6	15.2	17.9	21.3
R&D	8.2	2.2	0.0	2.3	(0.0)	1.9	1.8	2.0	2.2	4.3	4.7	4.0	3.4	2.7	2.9	2.9	2.9	3.0
Operating Expenses	7.5	1.1	3.7	4.8	2.5	4.1	6.7	3.5	3.6	7.0	57.4	75.2	79.0	83.0	87.1	91.5	96.0	100.8
Total operating expenses	15.7	3.3	3.8	7.1	2.5	6.0	8.5	5.6	5.8	11.3	63.2	82.3	87.3	93.2	101.6	109.5	116.9	125.1
Income (loss) from operations	(15.7)	(3.3)	(3.8)	(7.1)	(2.5)	(6.0)	(8.5)	(5.6)	(5.8)	(11.3)	(52.2)	(50.1)	(32.1)	(2.4)	47.1	97.0	142.5	203.1
Interest income (expense)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other non-operating income (expense)	(1.1)	(0.8)	(0.1)	(0.9)	(0.1)	(0.4)	(0.4)	-	-	-	-	-	-	-	-	-	-	-
Total non-operating income	(1.1)	(0.8)	(0.1)	(0.9)	(0.1)	(0.4)	(0.4)	-	-	-	-	-	-	-	-	-	-	-
Earnings (loss) before taxes	(16.8)	(4.1)	(3.9)	(8.0)	(2.6)	(6.4)	(8.9)	(5.6)	(5.8)	(11.3)	(52.2)	(50.1)	(32.1)	(2.4)	47.1	97.0	142.5	203.1
Provision (benefit) for income taxes	(0.0)	(1.4)	(1.8)	(3.3)	0.0	0.0	0.0	-	-	-	-	-	-	-	-	-	-	55.9
Net income (loss)	(16.8)	(2.7)	(2.0)	(4.7)	(2.6)	(6.4)	(8.9)	(5.6)	(5.8)	(11.3)	(52.2)	(50.1)	(32.1)	(2.4)	47.1	97.0	142.5	147.3
Other comprehensive gain (loss)	0.1	(0.5)	0.3	(0.2)	(0.3)	(0.3)	(0.7)	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) attributable to common stockholders	(\$16.6)	(\$3.2)	(\$1.7)	(\$4.9)	(\$2.9)	(\$6.7)	(\$9.6)	(\$5.6)	(\$5.8)	(\$11.3)	(\$52.2)	(\$50.1)	(\$32.1)	(\$2.4)	\$47.1	\$97.0	\$142.5	\$147.3
Basic EPS, GAAP	(\$0.57)	(\$0.08)	(\$0.05)	(\$0.12)	(\$0.07)	(\$0.17)	(\$0.24)	(\$0.15)	(\$0.15)	(\$0.30)	(\$0.89)	(\$0.85)	(\$0.54)	(\$0.04)	\$0.78	\$1.60	\$2.33	\$2.39
Diluted EPS, GAAP	(\$0.57)	(\$0.08)	(\$0.05)	(\$0.12)	(\$0.07)	(\$0.17)	(\$0.24)	(\$0.15)	(\$0.15)	(\$0.30)	(\$0.89)	(\$0.85)	(\$0.54)	(\$0.04)	\$0.78	\$1.60	\$2.33	\$2.39
Non-GAAP adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest (income) expense, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	2.5	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Depreciation and amortization	1.1	0.4	0.3	0.7	0.5	1.1	1.6	0.9	1.0	1.9	8.7	10.3	9.9	9.4	9.0	9.4	9.9	10.4
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Non-GAAP adjustments	1.1	0.4	0.3	0.7	0.5	1.1	1.6	3.4	3.5	6.9	13.7	15.3	14.9	14.4	14.0	14.4	14.9	15.4
Net income, Non-GAAP	(15.5)	(2.7)	(1.4)	(4.1)	(2.4)	(5.6)	(8.0)	(2.1)	(2.3)	(4.4)	(38.5)	(34.8)	(17.2)	(2.0)	61.1	111.4	157.4	162.7
Pro-forma EPS, Non-GAAP	(\$0.53)	(\$0.08)	(\$0.04)	(\$0.10)	(\$0.06)	(\$0.15)	(\$0.21)	(\$0.06)	(\$0.06)	(\$0.12)	(\$0.66)	(\$0.59)	(\$0.29)	\$0.20	\$1.01	\$1.84	\$2.58	\$2.64
Basic shares outstanding	29.3	33.6	39.5	39.5	37.4	37.4	37.4	37.6	37.8	37.8	58.7	59.1	59.5	59.9	60.3	60.7	61.1	61.5
Diluted shares outstanding	29.3	33.6	39.5	39.5	37.4	37.4	37.4	37.6	37.8	37.8	58.7	59.1	59.5	59.9	60.3	60.7	61.1	61.5

OKYO BS and CF statement (data in \$M)	2024A	1H25A	2H25A	2025A	1H26A	2H26A	2026A	1H27E	2H27E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
Net Cash	1	0	1	1	3	15	15	9	5	5	112	72	50	57	113	219	372	529
Cash and cash equivalents	0.8	1.0	1.6	1.6	4.2	14.6	14.6	10.0	5.1	5.2	111.7	71.9	49.7	56.7	112.8	219.3	371.7	529.4
Debt	-	0.6	1.0	1.0	1.0	-	-	1.0	-	-	-	-	-	-	-	-	-	-
Change in cash	(3.3)	0.2	0.6	0.7	2.7	10.4	13.0	(4.6)	(4.8)	(9.4)	106.5	(39.8)	(22.2)	7.0	56.1	106.4	152.4	157.7
Cash Flows from Operations	(9.5)	(0.2)	(1.6)	(1.8)	(1.5)	(4.4)	(5.9)	(2.1)	(2.3)	(4.4)	(38.5)	(34.8)	(17.2)	12.0	61.1	111.4	157.4	162.7
Net Income	(16.8)	(2.7)	(2.0)	(4.7)	(2.6)	(6.4)	(8.9)	(5.6)	(5.8)	(11.3)	(52.2)	(50.1)	(32.1)	(2.4)	47.1	97.0	142.5	147.3
SG&A	1.1	0.4	0.3	0.7	0.5	1.1	1.6	0.9	1.0	1.9	8.7	10.3	9.9	9.4	9.0	9.4	9.9	10.4
D/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	2.5	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Other	6.2	2.0	0.1	2.2	0.5	0.9	1.4	-	-	-	-	-	-	-	-	-	-	-
Cash Flows from Investing	-	-	(0.0)	(0.0)	-	(6.0)	(6.0)	(2.5)	(2.5)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)
CapEx	-	-	(0.0)	(0.0)	-	(6.0)	(6.0)	(2.5)	(2.5)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)	(5.0)
Other	-	-	-	-	-	(6.0)	(6.0)	-	-	-	-	-	-	-	-	-	-	-
Cash Flows from Financing	6.2	0.6	2.1	2.7	4.3	20.7	25.0	-	-	-	150.0	-	-	-	-	-	-	-
Equity raise/options exercise (buyback)	6.2	-	1.7	1.7	4.3	20.7	25.0	-	-	-	150.0	-	-	-	-	-	-	-
Debt raise (payback)	-	0.6	0.4	1.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	0.0	(0.0)	(0.0)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Note: Non-Cash Conversion of Debt	-	-	-	-	-	(1.0)	(1.0)	-	-	-	-	-	-	-	-	-	-	-
FX	-	(0.2)	0.0	(0.1)	(0.1)	0.1	(0.0)	-	-	-	-	-	-	-	-	-	-	-

Source: Piper Sandler estimates & company filings

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R: Resuming Coverage
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S: Suspending Coverage
OW: Overweight
N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

Distribution of Ratings/IB Services Piper Sandler				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OW]	497	61.97	141	28.37
HOLD [N]	295	36.78	48	16.27
SELL [UW]	10	1.25	2	20.00

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