OKYO Pharma

Targeting underserved corneal diseases

OKYO Pharma is advancing lead candidate urcosimod (previously OK-101) for neuropathic corneal pain (NCP), an area of unmet need with no approved treatment, as well as for inflammatory dry eye disease (DED). OKYO reported positive top-line data in early 2024 from its 240-patient Phase IIb study of urcosimod in patients with DED, showing improvements on both 'symptom' and 'clinical sign' endpoints. The company is engaging with the FDA to determine its next steps for urcosimod development in DED. Given the molecule's distinctive capability to also target pain, NCP may offer a further differentiated development pathway and this underscores OKYO's focus on the Phase IIb study in NCP.

Targeting pain and inflammation

Urcosimod, a lipid-conjugated peptide targeting the chemerin receptor, is associated with anti-inflammatory and pain-reducing properties, a potentially unique combination suited for treating NCP. While NCP does not usually cause vision loss, it is a potentially debilitating chronic ocular condition leading to severe corneal and periocular pain, and light-sensitivity. NCP can occur after nerve injury, such as from infection, refractive surgery or chronic DED. Abnormal nerve regeneration or sensitization then causes significant corneal discomfort. Its specific prevalence is uncertain but NCP may occur in c 10% of refractive surgery patients and possibly a comparable percentage of DED patients. No FDA-approved treatment currently exists for NCP, offering urcosimod a potential first-mover advantage.

Phase IIb NCP study data expected in mid-CY25

Supported by preclinical data showing pain reduction in an NCP mouse model, and a significant pain symptom score improvement in OKYO's Phase IIb DED study, the company began patient dosing in October 2024 in a 12-week placebo-controlled single-center Phase IIb study in NCP patients. OKYO recently announced plans to accelerate urcosimod development for the treatment of NCP by closing the study early. It expects to complete data analysis by mid-CY25 of the 17 patients who have completed the trial, and to then meet with the FDA to discuss steps towards a multi-center and, potentially, registrational trial.

Valuation: Undemanding enterprise value of $49m

In January, OKYO reported $1m in net cash as of 30 September and had since raised an additional $1.8m. OKYO estimates its cash burn rate for CY25 to be c $4m and hence will likely need to raise additional funds during the year. Positive data from the NCP study could drive a material re-rating above the current enterprise value, given the lack of approved treatment options for the condition.

Consensus estimates

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
3/24	0.0	(16.8)	(0.57)	0.00	N/A	N/A
3/25e	0.0	(7.5)	(0.17)	0.00	N/A	N/A
3/26e	0.0	(6.8)	(0.17)	0.00	N/A	N/A

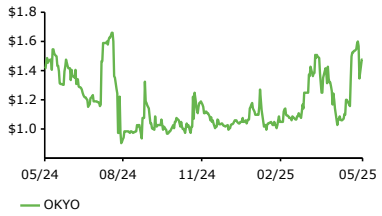
Source: Company data, HC Wainwright & Co

Healthcare

6 May 2025

Price	**$1.50**
Market cap	**$46m**

Share price performance



Share details

Code	OKYO
Listing	NASDAQ
Shares in issue	33.8m
Net cash at 30 September 2024	$1.0m

Business description

OKYO Pharma is a clinical-stage biopharmaceutical company developing therapeutic compounds to treat ocular indications including dry eye disease and neuropathic corneal pain.

Bull points

- Lack of approved treatments for NCP provides a market opportunity for the first approved drug.
- Urcosimod's dual analgesic and anti-inflammatory properties may distinguish it from other drugs used or under development for corneal disorders.
- DED represents a significant market opportunity (affecting over 15 million Americans), representing an addressable market of c $3bn in the US alone.

Bear points

- The DED landscape is increasingly competitive as both pharmaceutical and non-pharmacological (eg intense pulsed light, thermal pulsation) treatment options are available to patients.
- OKYO is exposed to clinical, drug development and regulatory risks.
- The company requires additional funding to advance its programs and is therefore subject to fund-raising related risks.

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