



May 9, 2023

OKYO PHARMA LIMITED

(NASDAQ: OKYO)

Industry: BioPharma

6-9 Mo. Price Target: \$5.50

OKYO PHARMA LIMITED

Innovative BioPharma Set to Enjoy Major Re-Valuation in 2023

Rob Goldman
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May 9, 2023

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COMPANY SNAPSHOT

OKYO Pharma Limited is a life sciences company focused on the discovery and development of novel molecules to treat inflammatory dry eye diseases and ocular pain. The Company's lead candidate to treat dry eye disease, OK-101, is currently in Phase II clinical trials in the US.

KEY STATISTICS

Price as of 5/8/23	\$2.13
52 Week High – Low	\$7.00 - \$1.10
Est. Shares Outstanding	25.5M
Market Capitalization	\$54.3M
Average Volume	681,923
Exchange	NASDAQ

COMPANY INFORMATION

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 Phone : 212.209.3998

INVESTMENT HIGHLIGHTS

OKYO is poised to emerge as a key player in the Dry Eye Disease (DED) treatment market. Based on its preclinical studies, we believe OKYO could offer advantages over existing therapies, which are not viewed favorably by clinicians. These include fewer side effects, along with reduced inflammation and pain.

The ocular company industry and the DED sub-segment, are huge and growing at a rapid rate. The global DED market is expected to reach \$6.54 billion in 2027, up from about \$5.2 billion in 2019.

OKYO just commenced a Phase II clinical trial with the objective of measuring safety and efficacy of OK-101 in DED patients, along with secondary endpoints such as ocular pain. A serious issue among a number of DED sufferers, there is no FDA approved product for neuropathic pain.

Top-line data from the trial is scheduled for release by year-end 2023 and serves as a major milestone for OKYO. We believe it is the catalyst for a re-valuation for the stock and for a mid-tier or top-tier firm to enter into a partnership with OKYO.

Our 6–9-month price target for OKYO is \$5.50. This target is based on the NPV of forecasted sales, a discounted price/sales multiple, discounted back five years at a reasonable discount rate.

The ocular treatment segment has garnered major attention. A flurry of M&A has occurred at high valuations, and OKYO's peers also reflect these high valuation characteristics. We believe OKYO could emulate this trend in the future.

COMPANY OVERVIEW

The View from 30,000 Feet

In our view, London-based **OKYO Pharma Limited (NASDAQ: OKYO)** is on track to emerge as one of the leading players in the ophthalmic drugs segment of the stock market. OKYO appears to check all of the boxes one would seek in a mid-stage clinical drug company. These boxes include its current development success and path, its deep IP portfolio, and the leadership and experience of its management team. As a result, OKYO's lead candidate, OK-101, appears poised to solve an unmet need for 49 million sufferers in the US alone. Plus, this segment has been rife with M&A by larger players seeking to build or grow their respective presences in the ophthalmic (sometimes referred to as ocular) segment, and we believe OKYO is a future target.

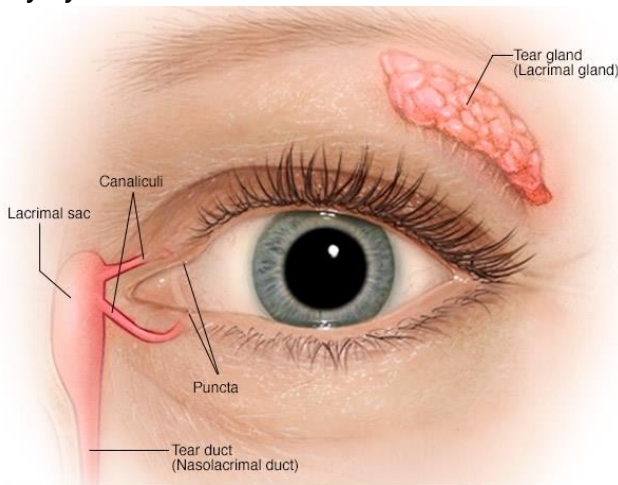
OKYO is focused on the discovery and development of novel molecules to treat inflammatory dry eye diseases and chronic pain and the topical solution OK-101 seeks to treat dry eye disease (DED), an estimated \$5.5 billion global market. OKYO recently commenced a multi-center, multi-arm, Phase II clinical trial in the US.

OK-101 was developed using a membrane-anchored-peptide (MAP) technology to produce a novel long-acting drug candidate for treating dry eye disease. OK-101 has been shown to produce anti-inflammatory and pain-reducing activities in mouse models of dry eye disease and corneal neuropathic pain; and is designed to combat washout through the inclusion of the lipid 'anchor' contained in the candidate drug molecule to enhance the residence time of OK-101 within the ocular environment. OK-101 is a lipid conjugated chemerin peptide agonist of the ChemR23 G-protein coupled receptor which is typically found on immune cells of the eye responsible for the inflammatory response.

What is DED?

According to the Mayo Clinic:

“Dry eye disease is a common condition that occurs when your tears aren't able to provide adequate lubrication for your eyes. Tears can be inadequate and unstable for many reasons. For example, dry eyes may occur if you don't produce enough tears or if you produce poor-quality tears. This tear instability leads to inflammation and damage of the eye's surface. Dry eyes are caused by a variety of reasons that disrupt the healthy tear film. Your tear film has three layers: fatty oils, aqueous fluid and mucus. This combination usually keeps the surface of your eyes lubricated, smooth and clear. Problems with any of these layers can cause dry eyes. Reasons for tear film dysfunction are many, including hormone changes, autoimmune disease, inflamed eyelid glands or allergic eye disease. For some people, the cause of dry eyes is decreased tear production or increased tear evaporation.”



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An estimated 700 million people suffer from DED worldwide, with 49 million sufferers in the US. DED affects more than 35% of people aged 50+, with women representing two-thirds of this segment. The prevalence of dry eye is expected to increase substantially going forward due to an aging population and the increased use of contact lenses and digital screen time.

Most observers and clinicians would characterize the current DED market's five FDA-approved products as subpar, or underwhelming. There are issues with efficacy, slow onset of action and a plethora of side effects. In contrast, evidence from OKYO's preclinical studies have indicated that OK-101 may reduce inflammation and ocular pain, and its core characteristics may enhance potency and reduce washout of the drug. It should be noted that there is no FDA-approved topical treatment for ocular pain, which could prove to be a gamechanger for OKYO in future trials.

The Phase II Trial: At a Glance

With the commencement of the Phase II clinical trial, OKYO has evolved from a preclinical biopharma company to mid-stage clinical development firm. It should be noted that skipping the Phase I stage (after meeting with the FDA) is a major boon, as it reduces the time to market by a few years. In addition to the rigor of the primary and secondary endpoints, the trial's primary objective is to compare safety and efficacy of OK-101 to placebo for the treatment of the signs and symptoms of dry eye disease.

Top-line data of the Company's Phase II clinical trial is planned for release by year-end 2023. In our view, this event is the key milestone that could prompt a major re-valuation of the Company and serve as a precursor to a potential investment or joint venture partnership with Big Pharma that can lead to a Phase III clinical trial and a possible, future FDA approval in 2026-2027.

Valuation

Given that the Company is primed to reach a key valuation-changing milestone with the release of Phase II top-line data, we have elected to publish a price target that we expect could be achieved in the next 6-9 months. If multi-dose data and efficacy match OKYO's primary and secondary objectives, we believe that this data could serve as a catalyst for a mid-tier – to top tier pharmaceutical firm to seek to enter into an investment and related licensing or partnership arrangement with OKYO in exchange for future R&D.

It is common for Big Pharma to enter into a partnership with firms that have successfully completed Phase II clinical trials and would need to raise substantial funds to design and execute a Phase III trial, along with commercializing a potentially FDA-approved product. We believe that such an event is in the cards for OKYO, perhaps even shortly after the release of top-line Phase II data. Against this backdrop, we envision a potential investment of tens of millions for future R&D, with additional funds to be invested based on R&D and other milestones, and a potential right to acquire a majority stake in OKYO.

Our 6-9-month price target is \$5.50 and is designed to reflect the potential valuation used by a prospective Big Pharma partner following the completion of the Phase II trial. This figure reflects our \$90M in annual CY2027 sales forecast for an FDA-approved OK-101 and an assigned 3.5x sales multiple (a \$315M value), which is a nearly 50% discount to the current year P/S ratio assigned the Company's peers. We then discounted this figure

back 5 years at a 15% discount rate. Thus, we arrived at a NPV of \$156M, or \$5.50, based on a slightly higher than current share count of 25.5M shares outstanding due to a future funding to complete the Phase II trial.

The average Price/Sales multiples on two peers that have DED drugs in mid-late-stage clinical trials, are trading 6.3x 2023E sales and 4.5x 2024E sales. Therefore, we believe that our approach is a reasonable one.

OKYO TARGET MARKET; THE EYES HAVE IT

Dry Eye Disease

Dry eye disease, or keratoconjunctivitis sicca, is a common and often chronic problem, particularly in older adults. With each blink of the eyelids, tears spread across the front surface of the eye, known as the cornea. Tears provide lubrication, reduce the risk of eye infection, wash away foreign matter in the eye and keep the surface of the eyes smooth and clear. Excess tears in the eyes flow into small drainage ducts in the inner corners of the eyelids, which drain into the back of the nose.

People with dry eyes either do not produce enough tears or their tears are of a poor quality due to a deficient tear film lipid layer, which increases tear evaporation. Advanced dry eyes may damage the front surface of the eye and impair vision. Dry eyes can develop for many reasons, including age, gender, medications, medical conditions, and other factors. Tear film instability triggers chronic inflammation of the ocular surface which leads to symptoms of constant pain, itchiness, burning, visual impairment, etc.

DED affects more than 35% of people aged 50+, with women representing two-thirds of this segment. One reason why this segment may be more predisposed than men could be related to hormonal changes that occur after menopause. These hormonal changes affect the quantity and quality of the tear film, or layer of tear fluid that protects the eye.

The prevalence of dry eye is expected to increase substantially going forward due to an aging population and the increased use of contact lenses and digital screen time. On a global basis, the DED market is expected to grow from \$5.2B in 2019 to \$6.54B in 2027, according to Fortune Business Insights. The US market is projected to be around \$2.4B.

The Players, The Drugs, The Transactions

As noted above, there are a number of issues with the current FDA-approved drugs—and while there are meaningful sales in the market, they pale in comparison to what they could be, in the eyes of the companies, the clinicians, and the patients. Perhaps that is why a number of transactions have occurred on the M&A side and why a handful of firms of varying sizes are in the mid-late stages of the clinical trial process.

Limits of Current Standard of Care

5 FDA Approved Drugs on Market With Inadequate Efficacy, Slow Onset of Action, and Numerous Side Effects

	API	¹ Limitations
Restasis Allergan	0.05% cyclosporine	Delayed response, up to 6 months to improve symptoms, burning sensation when instilled ² 70% patients do not refill Rx at Month 12
Xiidra Novartis	5% LFA-1 antagonist	Eye Irritation and burning sensation, change in taste ² 70% patients do not refill Rx at Month 12
Cequa Sun Pharma	0.09% cyclosporine	Burning, pain upon instillation, blurry vision, UTI (side effects on label)
Eysuvis Alcon	0.25% loteprednol	Short-term treatment only (maximum 2 weeks)
Tyrvaya Viartis	0.03 mg / Inhalation Varenicline	Sneezing, cough & throat irritation (side effects on label)



¹ Side Effect profiles from Drug Labels

² White DE, (2020) Ocular Surgery News: Issue February 25, 2020

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Figure 1: FDA Approved DED Products

Source: OKYO Pharma Limited

The figure above illustrates the issues with the approved products by name and manufacturer. The first two drugs have likely generated the greatest annual sales figures. Allergan, which was acquired by **AbbVie (NYSE: ABBV)**, was the producer of *Restasis*, the “big name” in the DED treatment segment. The drug is an immunosuppressive medicine, which works to increase tear production by helping reduce inflammation associated with DED. In 2021, *Restasis* generated \$1.29B in sales for AbbVie. However, with the introduction of a generic version in 2022, sales declined substantially. Analyst estimates were reportedly \$665M initially but we believe actual full year sales may have been as low as \$436M. The active ingredient, cyclosporine, traces its roots to first use in 1983 and its subsequent 2003 approval for use by Allergan. Sun Pharma of India introduced *Cequa* in the US in 2018/2019 and comes in a liquid solution, whereas *Restasis* is a liquid emulsion. Importantly, both drugs use cyclosporine, although *Cequa* has nearly double the concentration (0.09% versus 0.05%).

Xiidra works by a completely different mechanism and when it was acquired by **Novartis (NYSE:NVS)** from **Takeda (NYSE:TAK)** in 2019 for \$3.4B, it had around \$400M in sales when acquired and \$487M reported sales in 2022. It should be noted this product is the only one approved for signs and symptoms of DED. Still, given its side effects, the market is waiting for something with a better safety and efficacy profile. Finally, the last two drugs on the list, one of which was acquired by **Alcon (NYSE:ALC)** and the other drug by **Viartis (NASDAQ:VTRS)**, have been less than stellar performers, totaling an estimated \$11M in sales in 2022. In fact, one of the products, *Tyrvaya*, has been sold twice in the past few years. It may not help that its delivery is into the nasal system, rather than the eye.

Table I: Ocular Company M&A

Company Name	Buyer	Sym	Min Price (mil)**	Acq Rev Figure	Price/Rev Multiple	Acq Details	DED Exposure	Deal Closed
Iveric Bio*	Astellas	ALPMY	\$5,900	\$119	49.6	Company	N	2023-24
Oyster Point	Viartis	VTRS	\$415	\$22	18.9	Company	Y	2023
Kala	Alcon	ALC	\$60	\$11	5.5	2 Drugs	Y	2022
Aerie	Alcon	ALC	\$930	\$140	6.6	Company	Y	2022
Takeda	Novartis	NVS	\$3,400	\$400	8.5	Xidra	Y	2019
Median (excl Iveric)			\$673	\$81	7.6			2022

* Deal announced May 2023

** Excl dev, sales, milestones

Sources: www.Yahoo!Finance.com, Company websites, GSCR

The table above is noteworthy both to illustrate the Ocular company M&A activity, but also the DED exposure in each deal and the high price/rev multiples, which, of the closed deals, were typically based on trailing twelve-month revenue. In the case of **Iveric Bio (NASDAQ: ISEE)**, the figure we used was for CY2024---which was still an incredibly high P/S multiple.

Today, the key, approved DED players are AbbVie (from the Allergan deal years ago), Alcon, Novartis, and Viartis. It is interesting to note that a handful of companies of varying sizes have DED products in either Phase II or Phase III trials.

Table II. OKYO Publicly-Traded Peer Group

Company Name	Symbol	Price (5/8/23)	Mkt Cap (mil)	FY23E Revs (mil)	FY24E Revs (mil)	23E - 24E Revs Growth	2023E Price/Revs	2024E Price/Revs	DED Exposure
Aldeyra Thera*	ALDX	\$10.66	\$624	\$2	\$51	2450.0%	312.2	12.2	Phase III
Ocular Ther	OCUL	\$6.40	\$496	\$59	\$81	37.3%	8.4	6.1	Phase II
Palatin Tech	PTN	\$2.26	\$25	\$6	\$9	50.0%	4.2	2.8	Phase III
Average			\$382	\$22	\$47	44%	6.3	4.5	

* Excl ALDX 2023

Sources: www.Yahoo!Finance.com, Company websites, Goldman Small Cap Research

As illustrated in Table II, there are three OKYO peers that have exposure or drugs under development in the DED space. **Aldeyra (NASDAQ:ALDX)** has multiple products in the ocular space, including intravitreal injections, and is a pure play firm, in our view. The other two are pure plays as well but **Palatin (NYSE:PTN)** has had difficulties getting across the finish line. Given the high P/S figure for ALDX in 2023, our average P/S multiple excluded ALDX for the purposes of our future valuation and price targets.

In addition to these firms, Novaliq, a private company, has several products in the DED arena. These include approved devices in the EU, one drug about to enter Phase III in the US and two that may receive FDA approval ahead. One of these is yet another variation on cyclosporine at a slightly higher dose (0.1%). In our view, the

market would much rather see a different compound and mechanism of action, opening the door for OKYO and others. Interestingly, Aerie, acquired by Alcon, has a DED product in clinical trials, as does **Bausch & Lomb (NYSE: BLC)**, Stuart Therapeutics, and Mitotech.

It is worth monitoring these firms regarding their potential approval. The market is large and capable of offering major sales potential for a number of players. We also believe that it is possible that the legacy products get passed by the newcomers, going forward. These new approvals could drive market size growth as they gain traction. We believe this is why big firms have been so acquisitive and willing to pay high multiples as well.

THE OKYO DIFFERENCE

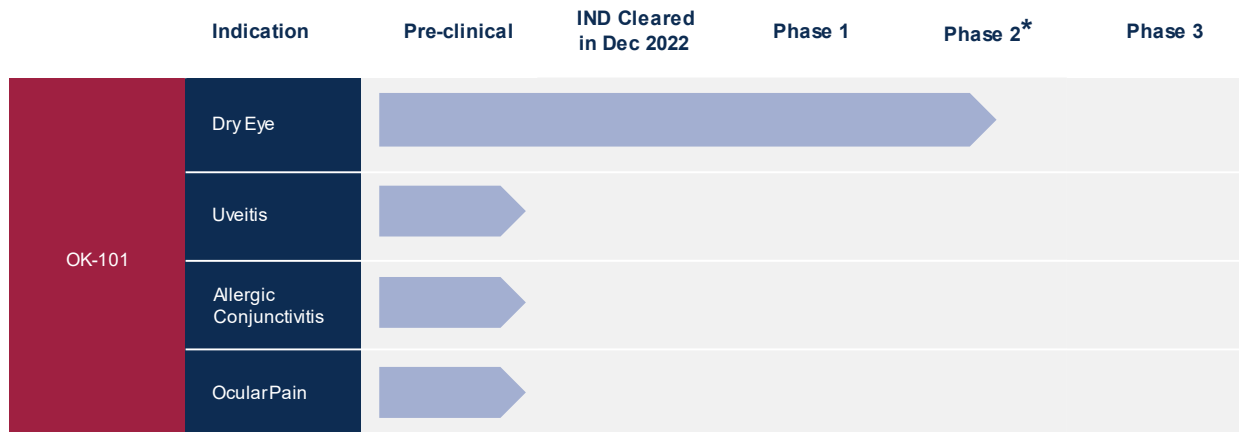
History

Tracing its roots to 2018, OKYO is a biopharmaceutical company developing next-generation therapeutics to improve the lives of patients suffering from inflammatory eye diseases and ocular pain. Its research program is focused on a novel G Protein-Coupled Receptor, or GPCR, which management believes plays a key role in the pathology of inflammatory eye diseases representing high unmet medical need. OKYO's therapeutic approach is focused on targeting inflammatory and pain modulation pathways that drive these conditions. OKYO is presently developing OK-101, its lead preclinical product candidate, for the treatment of dry eye disease ("DED"). The Company is also evaluating its potential in benefiting patients with ocular neuropathic pain, uveitis and allergic conjunctivitis.

The evidence from over 40 years of scientific literature suggests inflammation as the most common underlying characteristic of DED. An increase in the levels of inflammatory cytokines in both conjunctiva and tears is known to cause the chronic inflammation associated with DED. Consequently, development of new therapeutic agents that target inflammatory pathways is crucial in improving symptoms in DED patients. Moreover, a number of DED patients suffer from ocular neuropathic pain, making their condition more resistant to anti-inflammatory therapy, and a drug capable of targeting both of these aspects of DED would be a significant addition to the ocular-care practitioner's arsenal for the treatment of DED.

In 2018, OKYO successfully obtained (via assignment from Panetta Partners Limited, a related party) an exclusive license from On Target Therapeutics (OTTx) to patents owned or controlled by OTTx and a sub-license from OTTx to certain patents licensed by OTTx from Tufts Medical Center (TMC) to support its ophthalmic disease drug programs. These licenses gave OKYO the right to exploit the IP estate which is directed to compositions-of-matter and methodologies for treating ocular inflammation such as DED with lipid-linked chemerin analogues. OKYO also has a license from TMC to a separate IP estate for treating symptoms of ocular neuropathic pain, uveitis and associated pain. The scope of the TMC IP granted use through the sublicense with OTT is commensurate with the scope of use of the IP granted to OTT from TMC. This intellectual property, which includes 3 patents related to OK-101 including technology, dry eye, and neuropathic pain, forms the basis of OKYO's OK-101 program.

Pipeline Focus: OK-101 to Treat Dry Eye Disease



*Start of Phase 2 Trial Announced on May 2, 2023



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Figure 2: OKYO Pipeline
 Source: OKYO Pharma Limited

The Science

The development of new drugs to treat DED has been particularly challenging due to the heterogeneous nature of the patient population suffering from DED, and due to the difficulties in demonstrating an improvement in both signs and symptoms of the disease in well-controlled clinical trials. OK-101 is designed to target a chemokine-like receptor 1, or CMKLR1, or CHEMR23, which is a G protein-coupled receptor expressed on macrophages, neutrophils, monocytes, plasmacytoid/myeloid dendritic cells, natural killer cells and nonhemopoietic cell types, such as endothelial and epithelial cells as well as neurons and glial cells in the dorsal root ganglion, spinal cord, and retina. Activation of CMKLR1 by its endogenous peptide ligand chemerin is known to generate a pro-inflammatory response, and peptide fragments of chemerin have been discovered to generate the opposite, producing an anti-inflammatory response. However, natural ligands for CMKLR1 have short half-lives due to rapid inactivation. Discovery of OK-101, a stable, high potency CMKLR1 agonist provided an important step toward the development of a new class of anti-inflammatory therapeutics that can be applied to the treatment of ophthalmic diseases including DED, uveitis and ocular pain.

Chemerin Derived Peptide: A Potential Regulator of Inflammation & Pain



Figure 3: OK-101 Snapshot
 Source: OKYO Pharma Limited

This lipid-conjugated chemerin peptide is a first-in-class drug candidate with anti-inflammatory and ocular pain reducing property. Importantly, the lipid conjugated peptide chemistry minimizes drug washout. Moreover, the membrane anchoring strength may improve both the potency and staying power of the therapy, along with corneal permeability and corneal integrity---potentially a major differentiator compared with some of the legacy, FDA-approved products.

The Company initiated a mouse model and rabbit study for OK-101. In the mouse model, OK-101 demonstrated key efficacy and improvement in secondary objectives as well. Further, OKYO's OK-101 was able to demonstrate a reduction in inflammatory biomarkers with just 0.04% concentration.

Validation: OK-101 Efficacy in Dry Eye Mouse Model

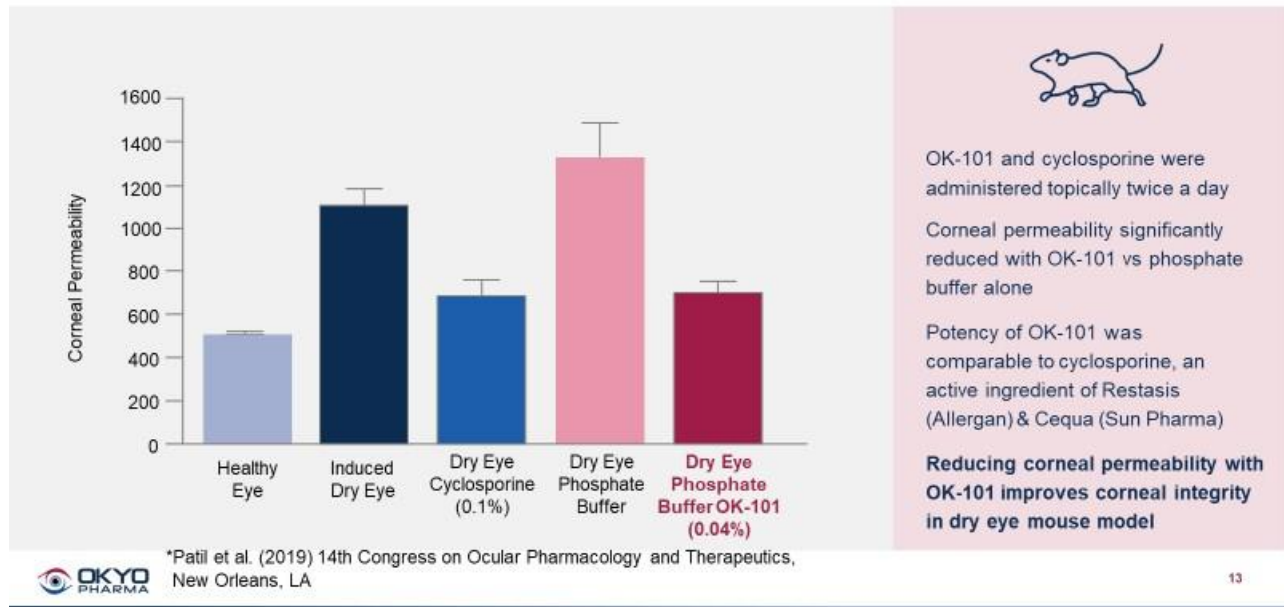


Figure 4: The Mouse Model
 Source: OKYO Pharma Limited

Based on early results from animal studies conducted by OKYO Pharma, OK-101 was first shown to be a promising candidate for the treatment of corneal inflammation, as shown in a mouse model of DED (Figure 4). In a separate set of animal model experiments, OKYO also evaluated the pain-reducing activity of OK-101 in a ciliary nerve ligation mouse model of corneal neuropathic pain. In collaboration with Pedram Hamrah, MD, an internationally recognized cornea specialist, and Co-Director of the Cornea Service and Director of the Center for Translational Ocular Immunology at New England Eye Center at Tufts medical Center, OKYO demonstrated that OK-101 suppresses corneal neuropathic pain in a mouse model of ciliary nerve ligation developed in Dr. Hamrah's laboratory (Figure 5). OK-101 was topically administered to mice in comparison to the positive control gabapentin which was administered via intraperitoneal injection. Pain relief was evaluated by an eye-wipe count, and OK-101 was shown to reduce corneal pain similar to that of gabapentin, a commonly used anticonvulsant oral drug typically used to treat neuropathic pain for conditions such as shingles and other systemic nerve pain disorders. Notably, the drug concentration of OK-101 used in this study was identical to that used in mouse models of DED that demonstrated ocular anti-inflammatory activity. OK-101 had no neurotoxic effect and did not affect the corneal epithelial integrity.

OK-101 Reduced Corneal Neuropathic Pain in Mouse Model

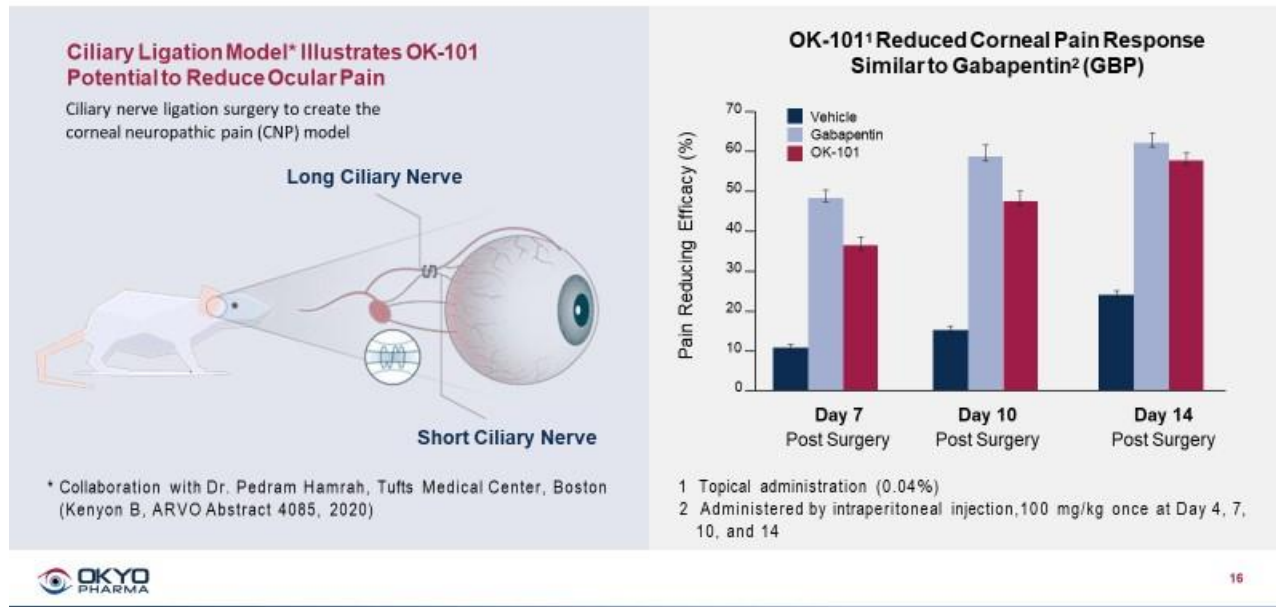


Figure 5: Reduced Corneal Neuropathic Pain in Mouse Model
 Source: OKYO Pharma Limited

To date, there is no FDA-approved topical treatment for ocular pain. Such patients would benefit from a drug that comprises anti-inflammatory and neuropathic pain reducing characteristics. ChemR23 receptor on leukocytes targeted by OK-101 is also expressed on neurons and glial cells in the dorsal root ganglion and spinal cord, which affirms the Company’s assessment of OK-101 for neuropathic pain.

Current treatments for neuropathic ocular pain are limited to short term NSAIDs, steroids, gabapentin, and opioids in severe cases. Neuropathic pain occurs through changes in both peripheral and central neurons leading to allodynia and hyperalgesia. Peripheral sensitization from the inflammatory cytokines during and after ocular surface injury alters responsiveness of peripheral sensory neurons, which initiates complex neuroinflammatory and electrophysiological signaling in the central nervous system that amplify the pain signaling.

OK-101 Addresses Inflammation and Pain Components of Dry Eye

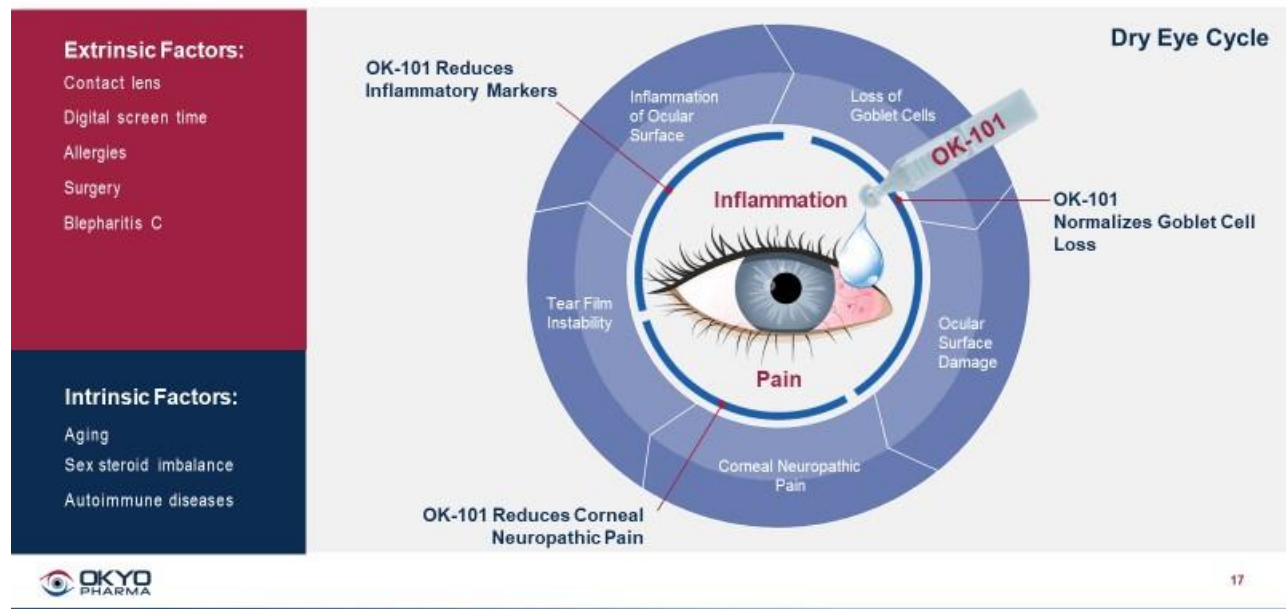


Figure 6: Anti-inflammatory and Pain Reducing Effects of OK-101 in Dry Eye
 Source: OKYO Pharma Limited

The Trial

OKYO held a Pre-IND meeting with the FDA in February 2022, whereby the FDA agreed with Company's plan to commence a Phase II human trial, rather than a Phase I. The FDA also agreed on pre-specified primary and secondary endpoints for the trial and cleared the IND in December 2022. As outlined above, OK-101 has shown in pre-clinical studies to have potent anti-inflammatory and neuropathic corneal pain activities, thus management is confident in the potential findings of the clinical trial.

Earlier this month, OKYO commenced the randomized, double-blinded trial, evaluating the efficacy and safety of OK-101 ophthalmic solution in subjects with dry eye disease (DED). The multi-center trial will have three arms: OK-101 Low Dose, OK-101 High Dose, and Placebo. The 240 subjects (which will likely skew more toward female over 50) will undergo dosing twice daily for 12 weeks (and also go through an initial 2-week run-in to deal with the standard placebo effect. Enrollment is slated to be completed by the end of July and it is anticipated that the trial shall last for 6-8 months. Top-line data will be available for release by year-end, as noted above.

The protocol for the study includes two prespecified primary endpoints and a number of secondary endpoints. Importantly, the Phase II trial protocol is designed to include pre-specified primary efficacy endpoints which are the hallmark of Phase III registration trials. Positive results would allow OKYO to expedite the program towards FDA approval by leveraging results from this trial in lieu of one of the two required Phase III trials to support U.S. marketing authorization.

We believe that the protocol's primary and secondary endpoints (safety and efficacy signs and symptoms) match those of prior clinical trials undergone by competing firms. We view this as a positive and note that any data that indicate pain improvement could prompt a follow-on study. Considering there is no FDA approved product for neuropathic or nerve damage pain, OKYO could prove to be sitting in the catbird seat for future studies and trials. Ora Inc., a premier clinical CRO (Contract Research Organization) in the ocular clinical trial space, is managing the Phase II trial and we believe that could have a tangible, favorable feature to the trial. Ora has led trials for multiple FDA approved ocular drugs.

Looking ahead, management may seek to engage in preclinical studies for other, related indications. Separately, although the US market is large, the rest of the world likely represents a similar size in the DED arena. We believe that if OKYO were to receive FDA marketing authorization, management may seek to license the drug to a player for the EU or APAC or both, rather than spend funds on R&D or potentially marketing. Our thesis remains that management seeks to eventually sell or license OK-101 for DED rather than spend funds to develop it alone in Phase III or attempt to build a marketing organization around it, should it receive FDA approval.

THE OKYO PHARMA LEADERSHIP TEAM

Gabriele Cerrone, Non-Executive Chairman

Mr. Cerrone has a successful track record and extensive experience in the financing and restructuring of micro-cap biotechnology companies. He has founded ten biotechnology companies in oncology, infectious diseases and molecular diagnostics, and has taken nine of these companies to the NASDAQ Market and two to the Main Market and AIM Market in London. Mr. Cerrone is Executive Chairman and Founder of Tiziana Life Sciences plc (NASDAQ:TLSA) a neuroinflammatory focused therapeutics company. Mr. Cerrone also co-founded Cardiff Oncology, Inc. (NASDAQ: CRDF), an oncology company and served as its Co-Chairman; he was a co-founder and served as Chairman of both Synergy Pharmaceuticals, Inc. (NASDAQ: SGYP) and Callisto Pharmaceuticals, Inc. (AMEX: CLSP), and was a Director of and led the restructuring of Siga Technologies, Inc. (NASDAQ: SIGA). Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc. and served as Chairman of the Board until its merger in September 2007 with Inhibitex, Inc. Mr. Cerrone served as a director of Inhibitex, Inc. until its US\$2.5bn sale to Bristol Myers Squibb Co in 2012.

Mr. Cerrone is also the Co-Founder of Rasna Therapeutics Limited (OTCMKTS: RASP), a company focused on the development of therapeutics for leukaemias; Co-Founder of Hepion Pharmaceuticals, Inc. (Nasdaq: HEPA); Executive Chairman and Co-Founder of Gensignia Life Sciences, Inc., a molecular diagnostics company focused on oncology using microRNA technology; and Executive Chairman and founder of Accustem Sciences plc; and founder of BioVitas Capital Ltd.

Gary Jacob, PhD, Chief Executive Officer

Dr. Jacob has over 35 years of extensive experience in the pharmaceutical and biotechnology industries across multiple disciplines, including research and development, operations, business development, capital financing activities and senior management expertise. He has developed broad and influential contacts throughout the biopharmaceutical, financial, banking and investor communities. Dr. Jacob is the Co-Founder and former CEO and Chairman of Synergy Pharmaceuticals. During his time at Synergy, he served as Chairman, Chief Executive

Officer and Executive Chairman, and is the co-inventor of Synergy's FDA-approved drug Trulance® which is currently marketed in the U.S. by Bausch Health, Inc. to treat functional GI disorders. Dr. Jacob is also the former CEO and Managing Director of Immuron Inc., an Australian biotechnology company dual-listed on the Australian ASX exchange and on NASDAQ. Dr. Jacob currently is Chairman of the Board of Hepion Pharmaceuticals, Inc., a public NASDAQ listed company with a drug in clinical development to treat non-alcoholic steatohepatitis (NASH) and is also on the Board of Directors of Cardiff Oncology, Inc., a NASDAQ listed public oncology company. He served as Chief Executive Officer and Director of Callisto Pharmaceuticals, Inc. from May 2003 until January 2013.

Prior to his involvement with Callisto and Synergy, Dr. Jacob was at Monsanto/G.D. Searle, where he was Director of Glycobiology and a Monsanto Science Fellow, specializing in the field of Glycobiology and drug discovery. Dr. Jacob holds over 30 patents and is the co-inventor of two pharmaceutical drugs which are FDA approved. Dr. Jacob earned a B.S. cum laude in Chemistry from the University of Missouri, St. Louis and holds a Ph.D. in Biochemistry from the University of Wisconsin, Madison.

Raj Patil, PhD, Chief Science Officer

Dr. Patil brings 30 years of ophthalmic experience and a powerful combination of academic scholarship and pharmaceutical R&D excellence.

Raj previously worked with Ora Inc, as Vice President of Research & Development, where he was responsible for driving all anterior and posterior segment research of Ora's R&D Institute. Earlier in his career, he worked at iVeena Delivery Systems as Vice President of Advanced Ocular Delivery Systems. His tenure at iVeena included a two-year sabbatical in Singapore, where he served as an Associate Professor of Ophthalmology at DUKE/NUS Medical School and Principal Investigator at Singapore Eye Research Institute.

Raj also held a number of leadership roles at Alcon/Novartis Institute of Biomedical Research, including Associate Director of Research and Head of Molecular Pharmacology glaucoma and retina research. Prior to joining the business world, Dr. Patil served as an Associate Professor of Ophthalmology, Cell Biology & Genetics at University of Nebraska Medical Centre in Omaha and as an Assistant Professor of Ophthalmology, Molecular Biology & Pharmacology at Washington University in St. Louis.

Raj received his PhD in Biochemistry from National Chemical Laboratory/University of Pune, India and completed his postdoctoral training in Biochemistry and Molecular Biology at the University of Michigan, Ann Arbor, MI. He is the recipient of Olga Keith Wiess Special Scholar Award from Research to Prevent Blindness Foundation and NIH Director's New Innovator Award. Dr. Patil has authored over 50 peer-reviewed research articles and serves as reviewer and editorial board member for numerous journals and is frequently invited to lecture at academic and industry events.

Keeren Shah, Chief Financial Officer

Keeren Shah serves as our Chief Financial Officer. Ms. Shah currently also serves as the Finance Director of Tiziana Life Sciences LTD, Accustem Sciences Limited and Rasna Therapeutics Inc., having previously served as the Group Financial Controller for all businesses from June 2016 to July 2020. Prior to joining the Company,

Ms. Shah spent 10 years at Visa, Inc. as a Senior Leader in its finance team where she was responsible for key financial controller activities, financial planning and analysis, and core processes as well as leading and participating in key transformation programmes and Visa Inc.'s initial public offering. Before joining Visa, Ms. Shah also held a variety of finance positions at other leading companies including Arthur Andersen and BBC Worldwide. She holds a Bachelor of Arts with honours in Economics and is a member of the Chartered Institute of Management Accountants.

Willy Simon, Non-Executive Director

Willy Jules Simon is a banker and worked at Kredietbank N.V. and Citibank London before serving as an executive member of the Board of Generale Bank NL from 1997 to 1999 and as the chief executive of Fortis Investment Management from 1999 to 2002. He acted as chairman of Bank Oyens & van Eeghen from 2002 to 2004. Willy Simon has been the chairman of Bever Holdings, a company listed in Amsterdam, since 2006 and Chairman of Ducat Maritime since 2015. He is also a non-executive director of Tiziana Life Sciences plc.

John Brancaccio, Non-Executive Director

Mr. Brancaccio, a retired CPA, is a financial executive with extensive international and domestic experience in pharmaceutical and biotechnology for privately and publicly held companies. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio is currently a director of Cardiff Oncology, Inc., Hepion Pharmaceuticals, Inc., Rasna Therapeutics, Inc., and Tiziana Life Sciences plc.

Bernard Denoyer, Non-Executive Director

Bernard F. Denoyer has 49 years of financial management experience including his service as Senior Vice President, Finance and Secretary of development stage Synergy Pharmaceuticals, Inc, from July 2008 until FDA approval and his retirement in June 2017. Between 2004 and January 2013 Mr. Denoyer concurrently served as Principal Financial Officer of Synergy's former parent company, Callisto Pharmaceuticals, Inc. From October 2000 to December 2003, Mr. Denoyer was an independent consultant. Prior to this, Mr. Denoyer served as Chief Financial Officer and Senior Vice President of META Group, Inc. Mr. Denoyer earned his CPA with Ernst & Young in 1975. He received a master's Certificate of Accounting from the Kellogg Graduate School of Management in 1974, an MBA in Finance with honours from Columbia Business School in 1972 and a BA in Economics from Fairfield University in 1969. Mr. Denoyer is fluent in French and studied in Paris at l'Istitut d'Etude Politique et Economique in 1968. He is currently serving on the Board of Trustees for two not-for-profits, St. Edmunds Retreat, Inc. and Midwestern Connecticut Council on Alcoholism, Inc.

SCIENTIFIC ADVISORY BOARD

Napoleone Ferrara, MD, Board Member

Dr. Ferrara is a Professor at the University of California San Diego Medical Center and a member of The National Academy of Sciences and has received numerous prestigious awards, including the Lasker Award and the Breakthrough Prize in Life Sciences. His research on understanding the role of angiogenesis and vascular endothelial growth factor (VEGF) in cancer development, led to the discovery that VEGF is a key mediator of angiogenesis associated with intraocular neovascular syndromes. This pioneering research led to the clinical development of a humanized anti-VEGF Fab (Ranibizumab, Lucentis®), which has also been approved as a therapy for neovascular age-related macular degeneration (AMD), retinal vein occlusion and diabetic macular edema. Ranibizumab and other anti-VEGF agents have had a dramatic impact on the development of therapies for these blinding disorders. When Lucentis® (Ranibizumab) received FDA approval in late June 2006, the new macular degeneration drug was celebrated as a major medical breakthrough. Dr. Ferrara's research also led to the development and approval of humanized anti-VEGF mAbs (Bevacizumab; Avastin®) for cancer treatment, with Avastin® being one of the bestselling cancer drugs over the last two decades. Lucentis® and Avastin® collectively achieved over \$9 billion in sales last year.

Pedram Hamrah, MD, FRCS, FARVO, Board Member

Pedram Hamrah, MD is Co-Director of the Cornea Service and Director of the Center for Translational Ocular Immunology at New England Eye Center at Tufts Medical Center in Boston. Dr Hamrah's research interests focus on corneal immunology and neuroscience, ocular imaging (immuno-imaging), ocular surface diseases and corneal neuropathic pain. He is currently on faculty at the departments of Ophthalmology and Bioengineering at Tufts University, where he is the director of clinical research and director of the Center for Translational Ocular Immunology. In addition, he is a faculty member at the immunology, neuroscience, and cell, molecular and developmental biology graduate programs at the Sackler School of Graduate Biomedical Sciences at Tufts. Throughout his career, he has focused on discovery, patient care and teaching. Dr. Hamrah currently serves on over a dozen editorial boards, is the associate editor for The Ocular Surface and TVST, section editor for Eye and assistant editor at Ocular Immunology and Inflammation.

Jay S. Pepose, MD, PhD, FARVO

Dr. Pepose, a specialist in refractive surgery and corneal and external diseases, is the founder and Medical Director of the Pepose Vision Institute and held the Bernard Becker Chair in Ophthalmology and Visual Sciences at Washington University School of Medicine in St. Louis. He is a consultant to numerous ophthalmic drug and device companies and serves as a Director and Chief Medical Advisor for Ocuphire Pharma. Dr. Pepose has been involved in over 40 clinical research trials, including registration trials for dry eye drugs, and has been the recipient of R-01 grant support from the National Eye Institute. He has served on the editorial boards of numerous prestigious journals, including the American Journal of Ophthalmology, Investigative Ophthalmology & Visual Science (IOVS), Cornea, and The Journal of Refractive Surgery and has over 200 peer reviewed publications. Dr. Pepose, an ARVO Gold Fellow, is a recipient of the Cogan Award from the Association for Research in Vision and Ophthalmology (ARVO) and the Life Achievement Honor Award from the American Academy of Ophthalmology. Dr. Pepose received an A.B. and M.A. in neurophysiology from Brandeis University and

completed the M.D.-Ph.D. program at UCLA School of Medicine. He completed ophthalmology residency at the Wilmer Institute at the Johns Hopkins Medical Center and fellowship training at Georgetown University Medical Center.

FINANCIALS SNAPSHOT

Given that OKYO is pre-revenue and has a lean infrastructure, line items in the P&L are few, as they generally just encompass research and development and general and administrative expenses. The Company has a March fiscal year and we have endeavored to project expenses to coincide with the continuation and conclusion of the Phase II trial. It should be noted that OKYO plans to raise funds this year to complete the high relative cost of the clinical trial. We do not purport to know the structure of such a deal for the London-based firm but we attempt to add a proper number of shares for FY24, should it be largely a common stock offering.

Going forward, we believe that the final trial results will be available in the first half of calendar year 2024, and that a subsequent Phase III registration trial could commence in 2025. At this juncture, we preliminarily forecast that if a marketing approval should be awarded, it could occur in late 2026 or early 2027. Therefore, if the Company were able to secure a development and marketing partner, sales could begin in 2027 and potentially reach the level of \$90M, given the size of the market and its likely favorable differentiating features. Given the chronic nature of DED, we deem it possible that the Company and a partner could generate up to \$400M in sales in the first full three years. Still, for valuation purposes, considering the number of future years a forecast would entail, our near-term valuation and price target involve year one sales in 2027 only.

Separately, investors outside of the US may notice we did not notate the London Stock Exchange symbol for OKYO. The Company has initiated the de-listing of the shares on the LSE, effective later this week. Therefore, we did not deem it necessary to include this item.

Table III. OKYO Pharma Limited
Pro Forma Projected Income Statement
March Fiscal Year

	<u>FY22A</u>	<u>1H23A</u>	<u>2H23E</u>	<u>FY23E</u>	<u>FY24E</u>
TOTAL REVENUE	\$0	\$0	\$0	\$0	\$0
<i>Operating Expenses</i>					
Research & Development	(\$1,301,178)	(\$2,607,675)	(\$1,500,000)	(\$4,107,675)	(\$8,500,000)
General & Administrative	(\$4,916,388)	(\$2,936,714)	(\$3,000,000)	(\$5,936,714)	(\$3,200,000)
Total Operating Expenses	(\$6,217,566)	(\$5,544,389)	(\$4,500,000)	(\$10,044,389)	(\$11,700,000)
Operating Income (Loss)	(\$6,217,566)	(\$5,544,389)	(\$4,500,000)	(\$10,044,389)	(\$11,700,000)
<i>Operating Margin</i>	N/A	N/A	N/A	N/A	N/A
Other income (Expense)	-	-	-	-	-
Tax provision	\$786,521	-	-	-	-
Net Loss attrib to ord share	(\$5,431,045)	(\$5,544,389)	(\$4,500,000)	(\$10,044,389)	(\$11,700,000)
Other comprehensive loss:	-	-	-	\$0	-
For curr trans adj	(\$837,152)	(\$62,581)	(\$50,000)	(\$112,581)	(\$75,000)
Total Comprehensive Loss	(\$6,268,197)	(\$5,606,970)	(\$4,550,000)	(\$10,156,970)	(\$11,775,000)
Net Loss Per Share	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.02)	(\$0.02)
Sources: OKYO, SEC, GSCR					

RISK FACTORS

In our view, the Company's biggest risk is related to the prospective clinical trial success of OKYO's lead candidate, OK-101. If top-line results of the ongoing Phase II clinical trial are comparable to the Company's mouse model, we believe that would be viewed as statistically significant, and a success that can lead to the development of a Phase III trial. Moreover, it is possible that some of the data related directly to primary and secondary endpoints provide upside surprises. The next major risk is related to the ability of the Company to successfully attract a joint venture partner that could help fund a Phase III trial via research development investments and potentially pay royalties to market an approved product in the US. In our view, given that existing therapies are widely considered to be subpar, favorable top-line data could attract a number of prospective partners that have historically demonstrated a model that features external investment and M&A as a primary R&D path.

Other risks could come from competing firms with DED drugs under development that may be chronologically ahead of OKYO, or perhaps demonstrate greater efficacy in their clinical trials. Therefore, these competitors could attract partners prior to OKYO, making the execution of favorable joint ventures potentially challenging for the Company.

The aforementioned risks could come from larger competitors, existing firms, or new entrants. Still, these future concerns are consistent with firms of OKYO's size and standing. Moreover, we believe that OKYO's seasoned management team is prepared to overcome these hurdles and execute its R&D and business development objectives.

Volatility and liquidity are typical concerns for small cap and microcap stocks. An overriding financial benefit as a public company is the favorable access to and the availability of capital to fund research and development, product launches, marketing campaigns and other initiatives. Since the proceeds of any future funding for OKYO would be used in large part to advance its lead drug candidate, we believe that any dilutive effect from such a funding could be offset by related, future increases in market value.

VALUATION

Given that the Company is primed to reach a key valuation-changing milestone with the release of Phase II top-line data, we have elected to publish a price target that we expect could be achieved in the next 6-9 months. If multi-dose data and efficacy match OKYO's primary and secondary objectives, we believe that this data could serve as a catalyst for a mid-tier – to top tier pharmaceutical firm to seek to enter into an investment and related licensing or partnership arrangement with OKYO in exchange for future R&D. Against this backdrop, we envision a potential investment of tens of millions for future R&D, with additional funds to be invested based on R&D and other milestones, and a potential right to acquire a majority or outright stake in OKYO.

Our 6-9-month price target is \$5.50 and is designed to reflect the potential valuation used by a prospective Big Pharma partner following the completion of the Phase II trial. This figure reflects our \$90M in annual CY2027 sales forecast for an FDA-approved OK-101 and an assigned 3.5x sales multiple (a \$315M value), which is a nearly 50% discount to the current year P/S ratio assigned the Company's peers. We then discounted this figure back 5 years at a 15% discount rate. Thus, we arrived at a NPV of \$156M, or \$5.50, based on a slightly higher than current share count related to a future funding to complete the Phase II trial.

The average Price/Sales multiples on two peers that have DED drugs in mid-late-stage clinical trials, are trading 6.3x 2023E sales and 4.5x 2024E sales. Therefore, we believe that our approach is a reasonable one.

Looking ahead, it is instructive to review the flurry of ocular company M&A by Big Pharma since they have carried high valuations. As outlined in Table I on Page 7, the deals we described were sold for a median of 7.6x trailing twelve-month revenue, with one deal representing current year sales. It should be noted that the most recently announced deal, last week's proposed acquisition of Iveric Bio by Astellas Pharma, was for 49.6x 2024E revenue. If future endpoints and objectives are met, it is possible that an acquisition could be in the cards in 36-48 months.

CONCLUSION

OKYO is poised to emerge as a key player in the Dry Eye Disease (DED) treatment market. Based on its preclinical studies, we believe OKYO could offer advantages over existing therapies, which are not viewed favorably by clinicians. These include fewer side effects, along with reduced inflammation and pain. The ocular

company industry and the DED sub-segment, are huge and growing at a rapid rate. The global DED market is expected to reach \$6.54 billion in 2027, up from about \$5.2 billion in 2019.

OKYO just commenced a Phase II clinical trial with the objective of measuring safety and efficacy of OK-101 in DED patients, along with secondary endpoints such as ocular pain. A serious issue among a number of DED sufferers, there is no FDA approved product for neuropathic pain. Top-line data from the trial is scheduled for release by year-end 2023 and serves as a major milestone for OKYO. We believe it is the catalyst for a re-valuation for the stock and for a mid-tier or top-tier firm to enter into a partnership with OKYO.

Our 6–9-month price target for OKYO is \$5.50. This target is based on the NPV of forecasted sales, a discounted price/sales multiple, discounted back five years at a reasonable discount rate. The ocular treatment segment has garnered major attention. A flurry of M&A has occurred at high valuations, and OKYO's peers also reflect these high valuation characteristics. We believe OKYO could emulate this trend in the future.

Table IV. OKYO Pharma Limited

Balance Sheet: 9/30/22

Current Assets

Cash and cash equiv	\$705,046
Current taxation rec	\$492,619
Other receivables	\$564,790
Total Current Assets	\$1,762,455

Non-Current Assets

Prop and equip, net	\$5,601
Right to use assets	\$0
Total Non Current Assets	\$5,601

TOTAL ASSETS **\$1,768,056**

Current Liabilities

Trade and other payables	\$1,987,528
Related party payable	\$125,113
Lease liabilities-current	\$0
Total Current Liabilities	\$2,112,641

Non-Current Liab

Lease liabilities, non-curr	\$0
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TOTAL NON-CURRENT LIABILITIES **\$0**

TOTAL LIABILITIES **\$2,112,641**

SHAREHOLDER'S EQUITY

Share capital	125,830,402
Share options reserve	3,023,820
Warrants reserve	72,215
Conv Note Loan Reserve	0
For curr trans reserve	(11,300,059)
Retained deficit	(\$117,970,423)
TOTAL EQUITY	(\$344,685)
TOTAL LIABILITIES & EQUITY	\$1,768,056

Sources: OKYO and Goldman Small Cap Research

RECENT TRADING HISTORY FOR OKYO

(Source: www.StockCharts.com)





SENIOR ANALYST: ROBERT GOLDMAN

Rob Goldman founded Goldman Small Cap Research in 2009 and has over 25 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

ANALYST CERTIFICATION

I, Robert Goldman, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

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