UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 29, 2022

Ocuphire Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34079**	**11-3516358**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
37000 Grand River Avenue, Suite 120 Farmington Hills, MI		**48335**
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: **(248) 681-9815**

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	OCUP	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On March 29, 2022, Ocuphire Pharma, Inc. (the "Company") posted on its website an informational presentation regarding the results of its MIRA-3 Phase 3 trial in reversal of mydriasis. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On March 29, 2022, the Company issued a press release regarding the results of its MIRA-3 Phase 3 trial in reversal of mydriasis. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of such website addresses in this Current Report on Form 8-K by incorporation by reference of the press release is as inactive textual references only.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Investor Presentation Materials, dated March 29, 2022
99.2	Press Release, dated March 29, 2022
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OCUPHIRE PHARMA, INC.

By: /s/ Mina Sooch
Mina Sooch
Chief Executive Officer

Date: March 29, 2022

Exhibit 99.1

Ocuphire PHARMA

Restore Vision & Clarity

MIRA-3 Phase 3 Trial Results Conference Call

March 29, 2022

Disclosures and Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning the regulatory timelines, commercial timelines, cash runway, and future clinical trials in reversal of mydriasis (RM), presbyopia, night vision disturbance (NVD) and diabetic retinopathy (DR)/diabetic macular edema (DME), and the potential market opportunity in RM. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) the effects of COVID-19 on clinical programs and business operations, (ix) the success and timing of commercialization of any of Ocuphire's product candidates and (x) the maintenance of Ocuphire's intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by the Company from time to time with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

The Company makes no representation or warranty, express or implied, as to the accuracy or completeness of the information contained in or incorporated by reference into this presentation. Nothing contained in or incorporated by reference into this presentation is, or shall be relied upon as, a promise or representation by the Company as to the past or future. The Company assumes no responsibility for the accuracy or completeness of any such information. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

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Agenda and Participants

Second Phase 3 RM Trial Topline Readout as Planned in 1Q22

- Highlights and Overview
- Topline MIRA-3 Phase 3 Clinical Trial Results for Nyxol in Reversal of Mydriasis (RM)
- Reversal of Mydriasis Market Opportunity
- Upcoming Milestones
- Q&A

Participants

Mina Sooch, MBA, President and CEO
Jay Pepose, MD, PhD, Medical Advisory Board and Board Member
Mitch Brigell, PhD, Head of Clinical Development
Susan Benton, MBA, Corporate Board Member
Bindu Manne, Head of Market Development and Commercialization
Charlie Hoffmann, MBA, VP of Corporate Development and Operations
Amy Rabourn, MAcc, VP of Finance

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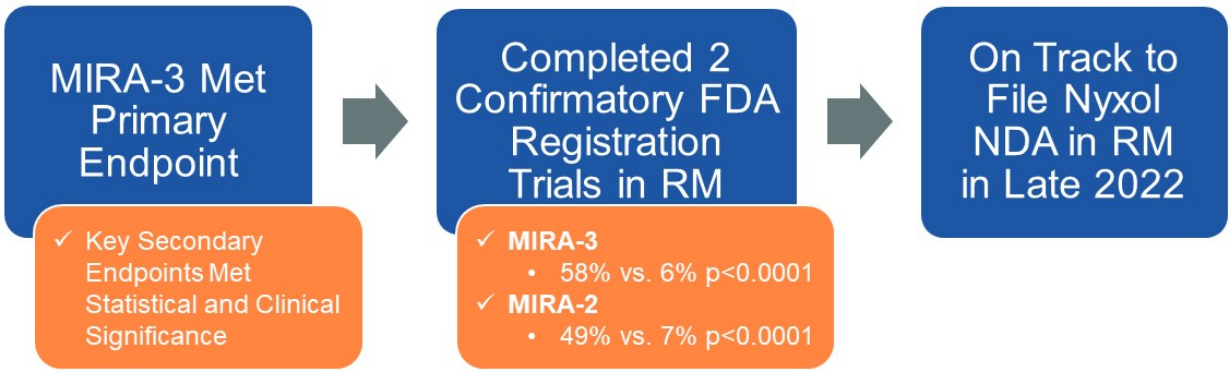
Highlights and Overview

Key Takeaways from Nyxol's MIRA-3 2nd Phase 3 RM Trial



MIRA-2 and MIRA-3 topline data.

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Addressing Unmet Needs in Large Markets

Significant Preclinical & Clinical Data Supporting MOA, Efficacy and Safety

Refractive

Nyxol®

Novel α1/α2 Blocker
505(b)(2)

10	>600	Exposure in Humans 28 Days	Patent Coverage 2034+
Completed Phase 1, Phase 2, and Phase 3 Trials	Subjects Dosed		

US Market Opportunity

RM **Reversal of Mydriasis** ~$500 M

P **Presbyopia** $10B - $20B

NVD **Night Vision Disturbances** $2B - $4B

Retina

APX3330

Oral REF-1 Inhibitor
New Chemical Entity (NCE)

11	>340	Exposure in Humans 365 Days	Patents to 2034+
Completed Phase 1 and Phase 2 Trials	Subjects Dosed		

DR **Diabetic Retinopathy**

DME **Diabetic Macular Edema**

US Market Opportunity

$10+B Oral Rx Revenues*

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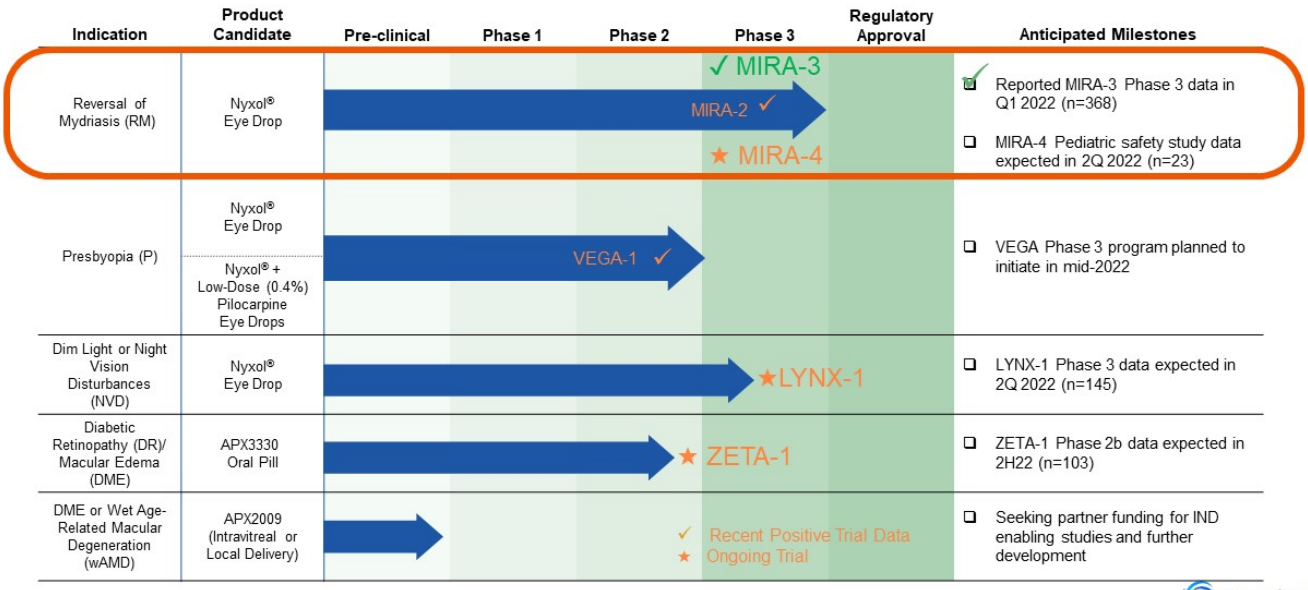
Source: Eisai and Apexian Data; GlobalData Market Research Report, 2020; Company Estimates for US Market Size; *Ocuphire internal estimates.

Ocuphire Pipeline & Clinical Milestones

Multiple Phase 3 & Phase 2 Clinical Data Readouts Anticipated this Year

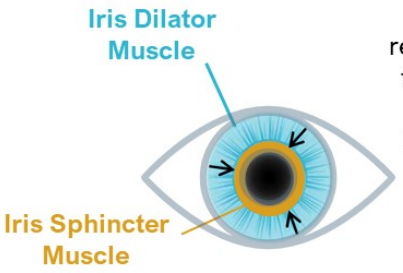


Note: 0.75% Nyxol (Phentolamine Ophthalmic Solution) is the same as 1% Nyxol (Phentolamine Mesylate Ophthalmic Solution)

Nyxol's Differentiated MOA as an Alpha-1 Blocker

Phentolamine Mesylate Reformulated as a Proprietary Topical Eye Drop ➔ Nyxol™

Phentolamine Mesylate is the Active Ingredient in Nyxol: a Non-selective α1 & α2 Antagonist

Blocking α1 Reduces Pupil Size	**Blocking α1** Dilates Blood Vessels
 Nyxol blocks α1 receptors only found on the Iris Dilator Muscle ↓ Decreases Pupil Size (Moderate Miosis) without Affecting the Ciliary Muscle	 Phentolamine mesylate is approved for 2 indications: • Regitine® (Pheochromocytoma) – intravenous injection approved in 1952 • OraVerse® (Reversal of oral anesthesia) – intramuscular injection approved in 2008 *505(b)(2) Regulatory Approval Pathway*

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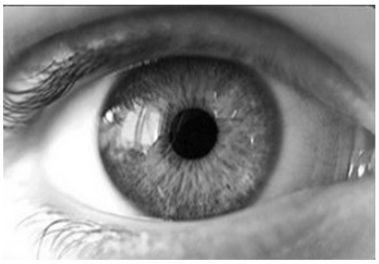
Nyxol Product Candidate Profile

Novel, Differentiated Alpha 1/2 Blocker Eye Drop for Refractive Indications

Nyxol: 0.75% Phentolamine Ophthalmic Solution
Preservative Free, EDTA Free, and Stable

Efficacy Data	Favorable Safety Profile	Durable
Nyxol Improves Vision by Decreasing Pupil (~1-1.5mm) ↑ Near Vision ↑ Distance Vision ↑ Contrast Sensitivity (night)	**No Systemic Effects** No Changes in Blood Pressure No Changes in Heart Rate **Well-Tolerated Topical Effects** Mild, Transient, Reversible Eye Redness **IOP Unchanged or Decreased** **Minimal to No Headaches**	**Effects Last ≥ 24 Hours** Chronic daily dosing of Nyxol at bedtime reduces pupil size for up to 24 to 36 hours

Nyxol® for Reversal of Mydriasis (RM)



"I had a premium cataract procedure by my MD, and I was unable to see clearly for two days. My doctor said it was due to my dilation. I did not expect my dilation to last that long."

"I have to visit my retina MD for my monthly injections, where I am dilated. Being dilated every month is a huge burden on my day."

RM

"I have to stay indoors. They say it only lasts a few hours, but it lasts all day, and it is very annoying."

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Problem: Dilated Eyes for Exams and Procedures

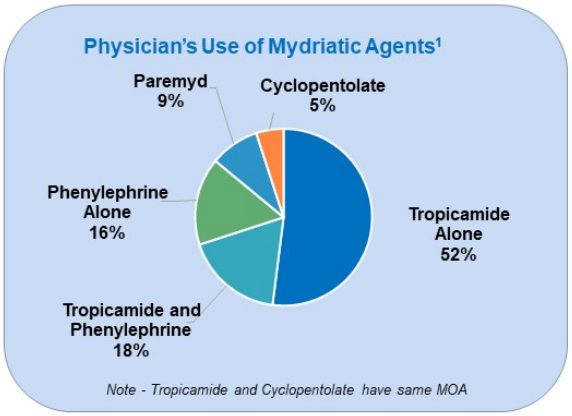
Patients Report Significant Side Effects after Dilated Eye Exam

The Problem

Pharmacologically-induced pupil dilation is part of standard care for annual and specialty eye exams…

…but there is 6 to 24 hours of impaired vision including:

- Inability to Focus
- Photophobia (sensitivity to light)
- Cycloplegia (loss of accommodation)
- Difficulty Reading and Driving
- Halos and Glare



NO REVERSAL DROPS COMMERCIALLY AVAILABLE

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1. GlobalData Market Research Survey; Oraverse and Regitine Label

RM

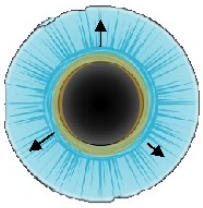
Nyxol Has Potential To Be The Only Option For RM

Physicians AVOID Use of Cholinergic Agonists (Pilocarpine) Due to Safety Risk on Ciliary Muscle

2 Classes of Mydriatic Agents

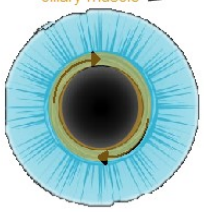
Phenylephrine (α1 agonist)

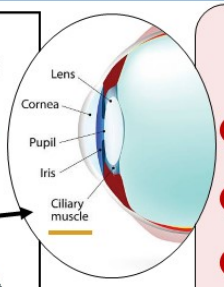
Sympathetic (primarily α1) innervation stimulates the iris dilator muscles



Tropicamide (anti-cholinergic)

Parasympathetic innervation stimulates the iris sphincter **and** ciliary muscle





Reversal via the Ciliary Muscle by Cholinergic Agonists* is Not a 'Safe' Option

- Retinal tear has been reported in some patients, especially high myopes[1]
- Induces accommodation spasm and reduction in distance vision[2]
- Induced anterior shift of the lens can increase the risk of acute angle-closure glaucoma[2]
- High incidence of brow ache and headache following installation[3]

Cholinergic Agonists include pilocarpine, carbachol, and aceclidine. Note, pilocarpine is rarely used off-label for RM given these safety concerns.

Nyxol® is the only eye drop in clinical development for multiple indications with a MOA that does not affect the ciliary muscle

1 Pilocarpine FDA Label (2017)
2. Optician (2012)- Mydriatic Drugs: Practical Considerations
3. Lee DA, Higginbotham EJ, 2005. Glaucoma and its treatment: a review. Am J Health Syst Pharm 62, 691–699.

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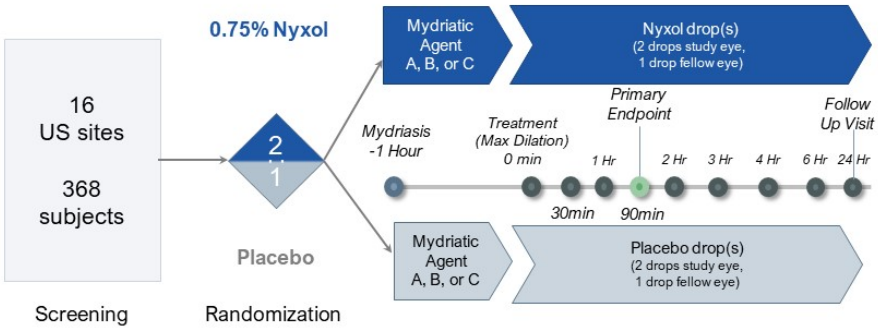
MIRA-3 Topline Phase 3 Results

Randomized, Parallel Arm, Double-Masked, Placebo-Controlled Study of the Safety and Efficacy of Nyxol (0.75% Phentolamine Ophthalmic Solution) to Reverse Pharmacologically-Induced Mydriasis in Healthy Subjects

MIRA-3 Phase 3 Registration Trial Design

Randomized, Double-Masked, Placebo-Controlled, Parallel, Multi-Center, One-Day Trial



Key Eligibility Criteria

Inclusion: Healthy ≥ 12 years of age

Exclusion: Clinically significant ocular trauma, surgery, or non-refractive laser treatment within the 6 months prior to screening; and recent or current evidence of ocular disease, infection or inflammation in either eye

MIRA-3 Started in Nov 2021 ➔ Enrolled 368 in Feb 2022
Phase 3 Results Reported March 2022

Endpoints

Primary: % of subjects (study eye) returning to baseline (within 0.2 mm) pupil diameter (PD) at 90 min

Key Secondary:

- % of subjects returning to baseline at 0min, 30min, 1h, 90 min 2h, 3h, 4h, 6h, 24h (overall, by mydriatic agent, by iris color)
- Mean time to return to baseline PD
- Mean change in pupil diameter at all timepoints
- Distance-Corrected Near Vision
- Accommodation (Tropicamide/Paremyd)
- Safety and tolerability

Mydriatic Agents 3:1:1 – A: 2.5% phenylephrine (alpha-1 agonist), B: 1% tropicamide (cholinergic blocker), C: Paremyd® (combination)

Demographics

Treatment and Placebo Arms Were Balanced in MIRA-3 Phase 3 Registration Trial

	Nyxol n=244	Placebo n=124	Total n=368
Demographics			
Age (years): Mean (Range)	34 (12-80)	36 (12-80)	35 (12-80)
Sex: Male n (%) **Female** n (%)	92 (37.7%) 152 (62.3%)	59 (47.6%) 65 (52.4%)	151 (41.0%) 217 (59.0%)
Race: White n (%) **African American** n (%) **Asian** n (%) **Other^** n (%) *^includes American Indian or Alaska Native; Native Hawaiian or Other Pacific Islander*	182 (74.6%) 38 (15.6%) 22 (9.0%) 0 (0%)	93 (75.0%) 21 (16.9%) 9 (7.3%) 1 (0.8%)	274 (74.5%) 59 (16.0%) 31 (8.4%) 7 (1.9%)
Light Iris Color: n (%)	113 (46.3%)	58 (46.8%)	171 (46.5%)
Dark Iris Color: n (%)	131 (53.7%)	66 (53.2%)	197 (53.5%)

Notes: ***32 pediatric subjects 12-17years old were enrolled in the trial.***
Race is more than 100% given subjects could check more than one category.
Demographics represent all randomized population (ARP) of 368 which is the same as Safety Population and Modified-Intent-to-Treat (mITT).
Per Protocol (PP) Population is 345, excludes 23 subjects who did not dilate more than 0.2 mm 1 hour after receiving mydriatic drop.

Source: MIRA-3 Table 14.1.2.1 (ARP) (mITT).

RM

Baseline Characteristics Study Eye

Treatment and Placebo Arms Were Balanced Across Ocular Measures in the MIRA-3 Trial

	Nyxol n=248	Placebo n=120	Total n=368
Baseline Characteristic			
Baseline Pupil Diameter Mean (mm)	5.1	4.9	5.1
Max Dilated Pupil Diameter Mean (mm)	7.2	7.1	7.2
Accommodation Mean (diopters)	7.4	7.6	7.5
BCDVA letters *55 letters = 20/20*	57	57	57
DCNVA letters *70 letters = 20/20*	65	65	65
IOP (mmHg)	16.2	16.1	16.1

Source: MIRA-3 Table 14.1.2.1 (ARP) (mITT).

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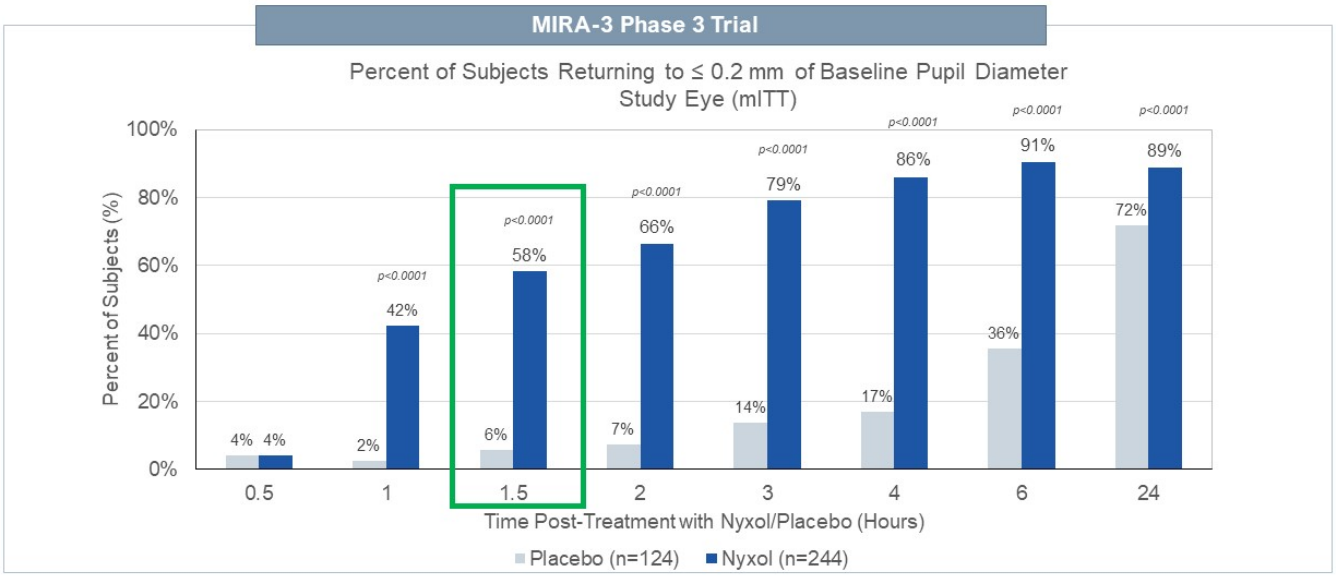
Primary Endpoint: 58% of Subjects' Study Eye Returned to Baseline at 90 Min

Nyxol Statistically Better Than Placebo Starting At 1 Hour And All Subsequent Timepoints

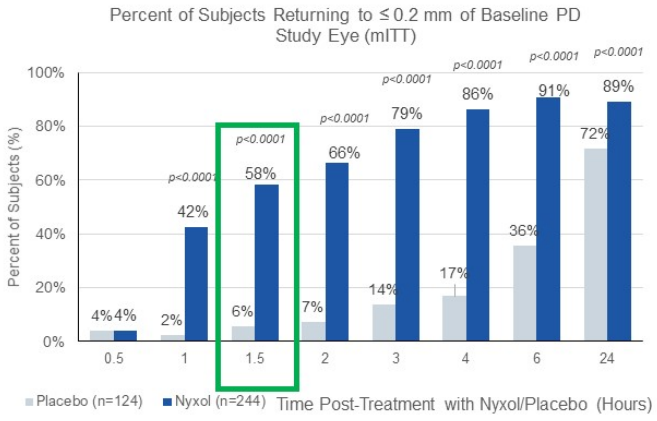


Source: MIRA-3 Table 14.2.1.1 (mITT). Data include all three mydriatics (Phenylephrine, Tropicamide, Paremyd).

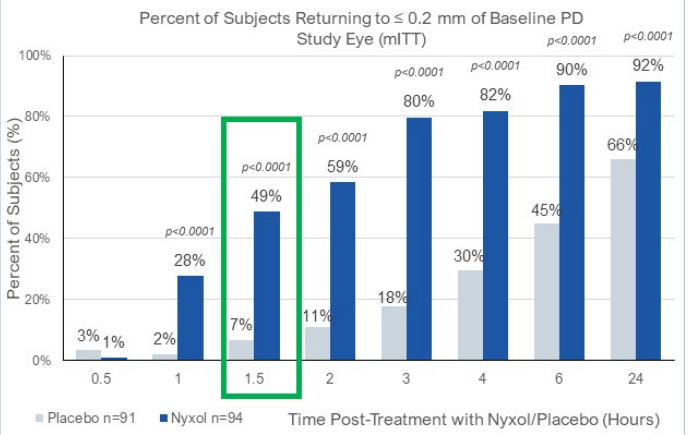
Primary Endpoint Achieved in Two FDA Registration Phase 3 Trials

Rapid, Consistent and Sustained Reversal of Pupil Dilation with Nyxol

MIRA-3 Phase 3 Trial



MIRA-2 Phase 3 Trial

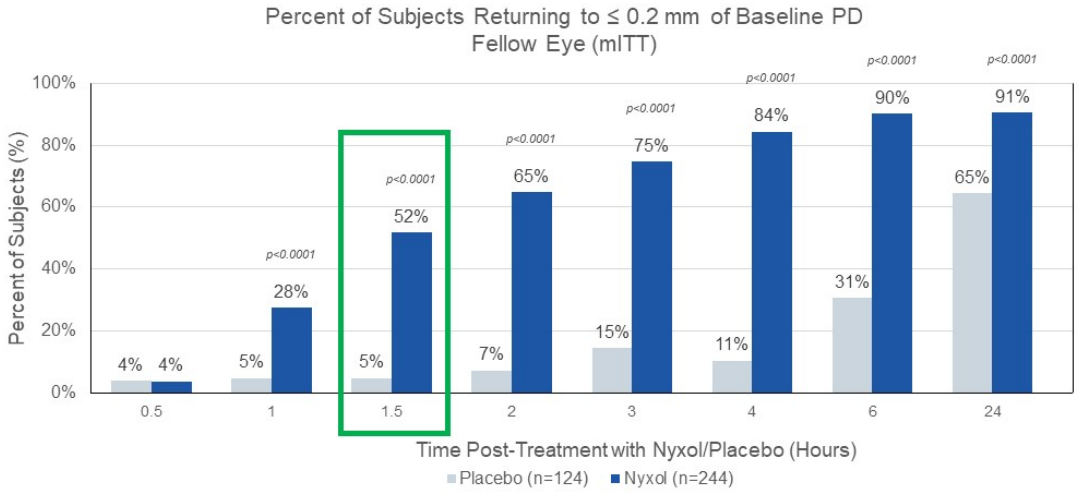


Source: (Left panel) MIRA-3 Table 14.2.1.1 (mITT); (Right panel) MIRA-2 Table 14.2.1.1 (mITT). Data include all three mydriatics (Phenylephrine, Tropicamide, Paremyd).

Comparison of One Drop (Fellow Eye) with Two Drops (Study Eye)

Similar 52% of Subjects Return to Baseline at 90 Minutes with a Single Drop of Nyxol

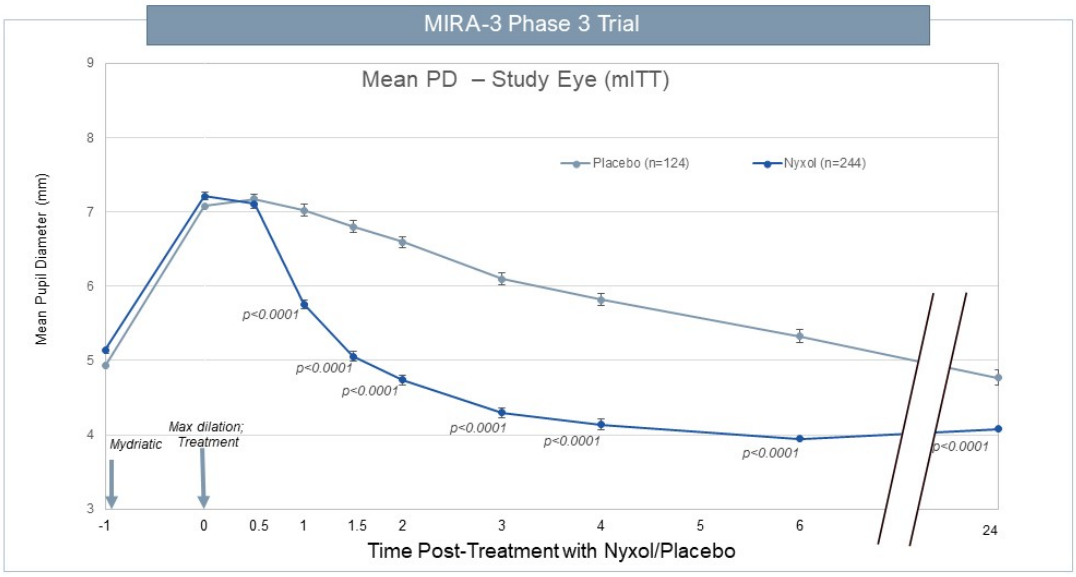
MIRA-3 Phase 3 Trial



Source: MIRA-3 Table 14.2.1.1 (mITT). Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd).

Mean Pupil Diameter Over Time

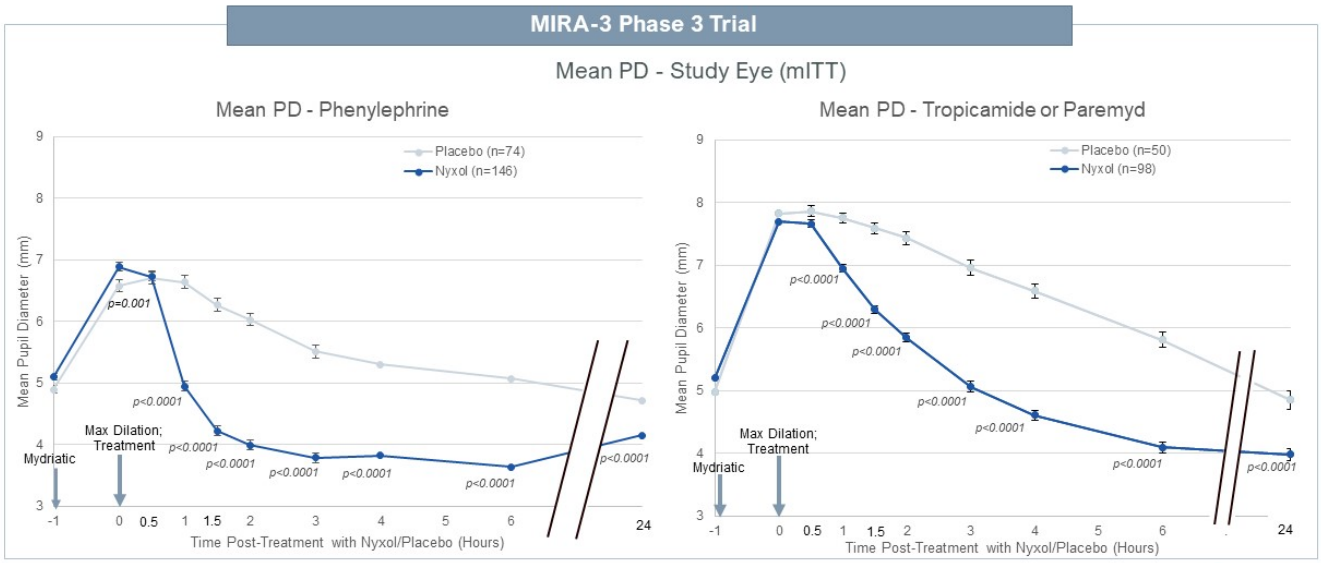
Nyxol Treatment Significantly Reduced PD Starting at 1 Hour Post-Dose Through 6 Hours



Source: MIRA-3 Table 14.2.2.1 (mITT). The p-values are change from max pupil dilation treatment compared to placebo.
Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd). Standard Error bars are shown.

Mean Pupil Diameter Over Time **by Mydriatic Agents**

Nyxol Reduced PD With All Mydriatic Agents; More Rapidly with Phenylephrine as Expected



Source: MIRA-3 Table 14.2.2.3. (mITT). The p-values are change from max pupil dilation treatment compared to placebo. Standard Error bars are shown.

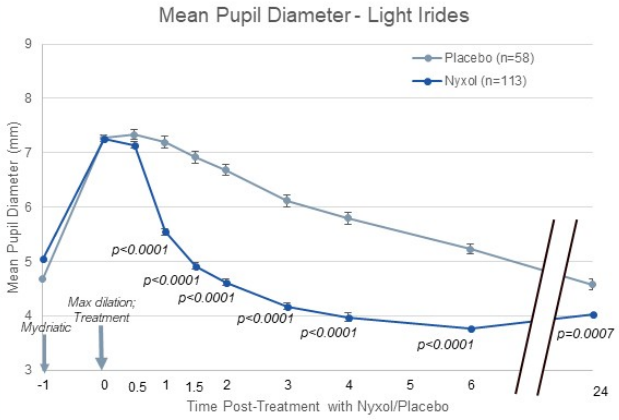
RM

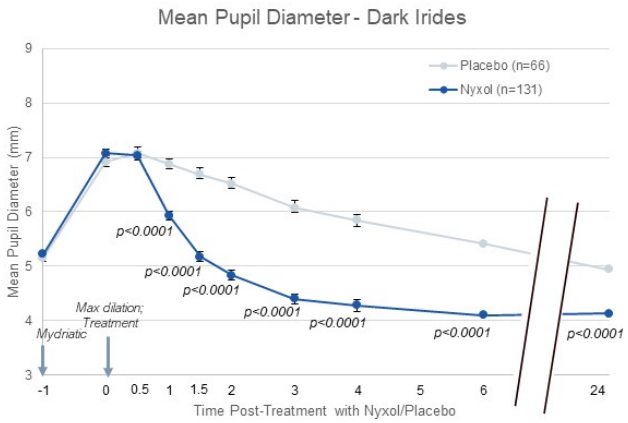
Mean Pupil Diameter Over Time **by Eye Color**

Nyxol Reduced Pupil Diameter Rapidly in Both Light and Dark Irides

MIRA-3 Phase 3 Trial

Mean PD - Study Eye (mITT)





Source MIRA-3 Table 14.2.2.5-(mITT). The p-values are change from max pupil dilation treatment compared to placebo.
Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd). Standard Error bars are shown.

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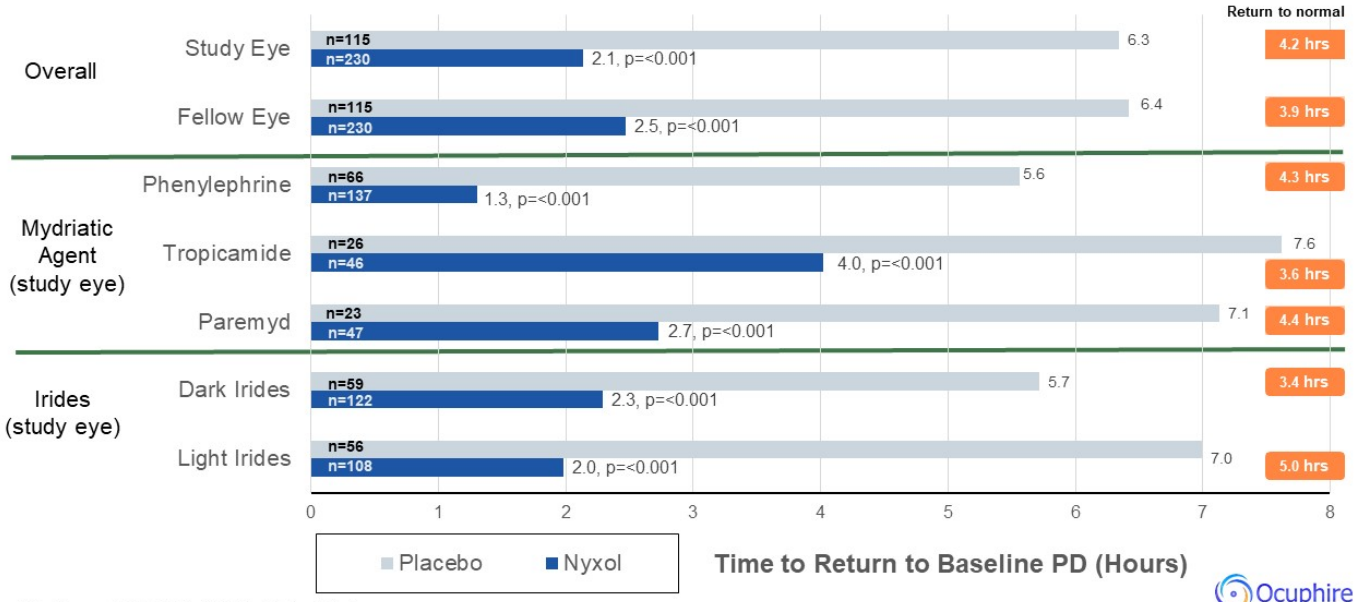
Mean Time to Return to Baseline PD

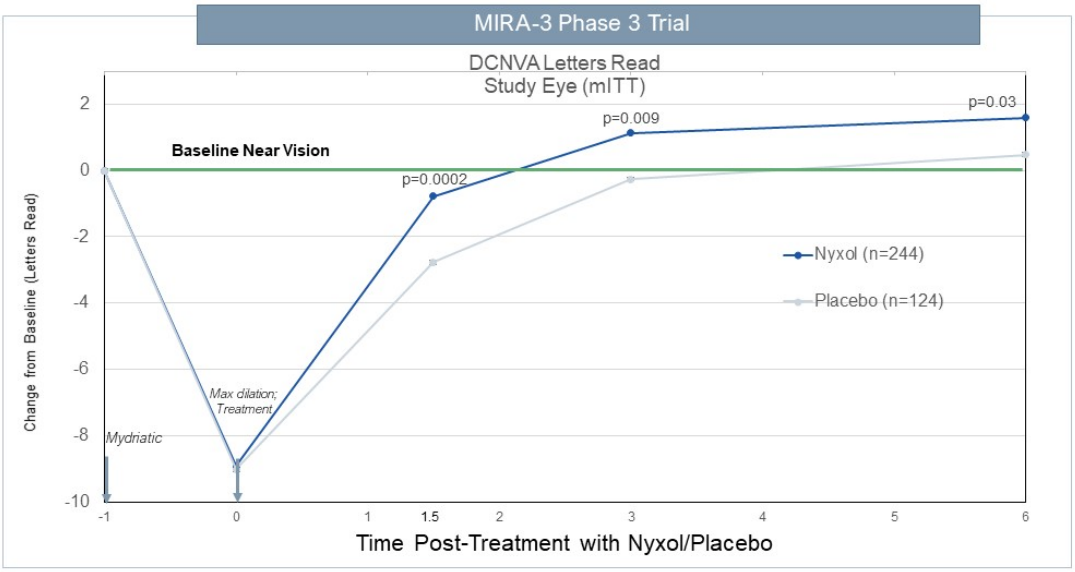
Saving of ~4 Hours in Return to Normal PD Overall and Across Mydriatic Agents



23 Source: MIRA-3 Table 14.2.3.2 (PP Population).

Maximum Pupil Dilation Results in Loss of Near Vision

Nyxol Returns Near Vision to Baseline Levels Statistically Faster Compared to Placebo



MIRA-3 Table 14.3.6.1.1 (Safety Population) (mITT). DCNVA- Distance-Corrected Near Visual Acuity.

RM

Summary of Safety Findings

Nyxol was Well Tolerated with a Favorable Safety Profile

- There were no deaths, serious AEs, or withdrawals due to AEs
- 48 of 244 (20%) Nyxol treated subjects reported 101 AEs
  - All treatment related AEs were mild in severity
- The only AE occurring in ≥ 5% of subjects treated with Nyxol, was conjunctival hyperemia (11% Nyxol vs. 0% placebo)
  - Less than 1% of subjects reported instillation site discomfort, pain, or irritation
- Conjunctival hyperemia was observed to be mild and transient
- Visual acuity (distance and near) was not adversely affected by Nyxol
- Over 300 subjects have been treated with Nyxol and evaluated at 24-hours in the MIRA trials → satisfying regulatory requirements for drug safety exposure for the acute RM indication

Source: MIRA-3 Table 14.3.1.1; MIRA-3 Table 14.3.1.2.2; MIRA-3 Table 14.3.3.2 (Safety Population).

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Summary of Positive MIRA-3 Phase 3 Results for Nyxol Eye Drops

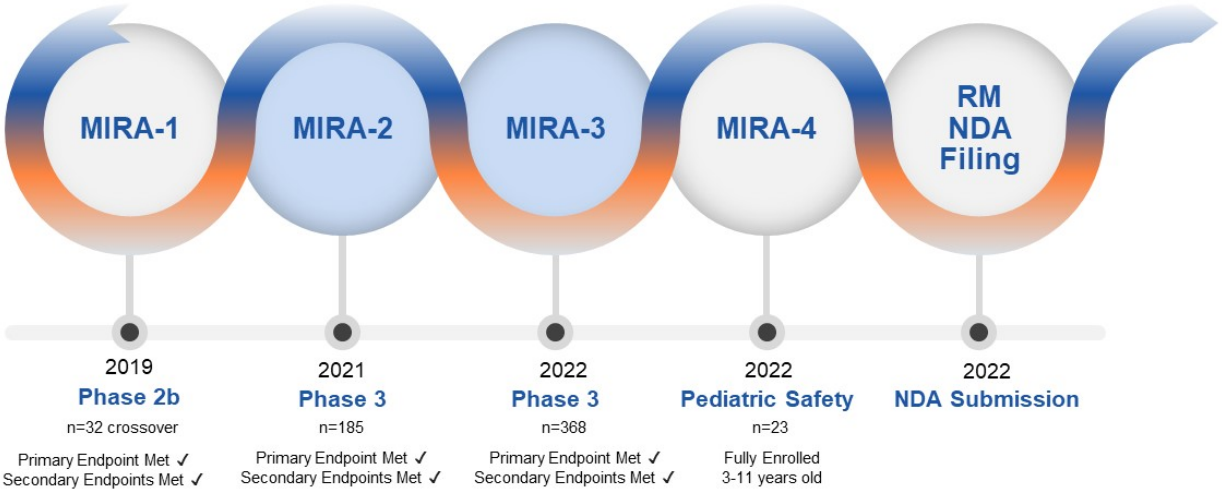
Confirms Prior Phase 3 Study Showing Substantial Benefit in Accelerating Reversal of Mydriasis

- **Met primary endpoint at 90 minutes with 58% of subjects returning to pre-dilation pupil diameter vs. 6% of placebo treated subjects (p < 0.0001)**
- **Saving of ~4 hours in time to return to normal pupil diameter**
- **Met key secondary endpoints with high statistical significance**
  - Efficacy seen at all timepoints from 60 minutes to 24 hours
  - Similar efficacy for one drop and two drops
  - Efficacy across all 3 mydriatic agents – phenylephrine, tropicamide, and Paremyd®
  - Efficacy in both light and dark iris colors
  - Accelerated return to normal distance-corrected near visual acuity
- **Favorable safety and tolerability profile**
  - No serious AEs, no drop-outs from AEs
  - No systemic or ocular AEs were observed in ≥ 5% of subjects, except for 11% mild, transient conjunctival hyperemia
- **NDA planned for late 2022**

Plans to NDA for Nyxol in RM

MIRA Program Evaluating Nyxol for the Reversal of Mydriasis

Efficient Clinical Programs have Positioned Ocuphire to Target NDA Filing in Late 2022



RM

NDA Submission Targeted in Late 2022

Potential Regulatory Approval in 2023

Target Label Indication

The treatment of pharmacologically induced mydriasis produced by adrenergic (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents, or a combination thereof.

Preservative-Free Single Unit Vial (5-pack)

Nyxol®

✓

P3 Clinical Trial

Completed 2nd Phase 3 trial in RM (enrolled 368 subjects), which also meets 24-hour safety population exposure requirement

Ongoing

Pediatric Safety

Enrolled 23 subjects ages 3 to 11 per agreed FDA initial pediatric study plan

Ongoing

Manufacturing

Completed 3 registration batches; 1-year CMC stability will be available for NDA

Regulatory Approval

Submit NDA by late 2022, with expected approval review of 10 months

Ocuphire PHARMA

Reversal of Mydriasis Market Opportunity

RM

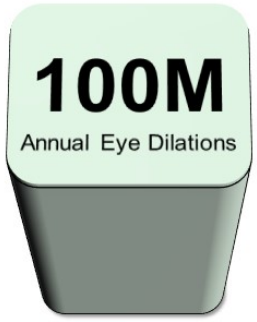
Reversal of Mydriasis Unmet Need & Landscape

With No Commercially Available Treatment, Nyxol is Uniquely Positioned as a New Reversal Drop

The Problem

- At many annual eye exams and specialty visits, pupils are pharmacologically dilated, impairing vision for **6-24 hours**
- Dilated eyes experience:
  - Heightened sensitivity to light
  - Inability to focus, headaches
  - Difficulty reading, working & driving
  - Halos and glare
  - Cycloplegia (loss of accommodation)

No Currently Available Treatments



Current Landscape:

- Rare off-label use of cholinergic agonists (e.g., pilocarpine) given ciliary muscle safety issues[1,2]
- Optomap® is offered by optometrists to avoid dilations for ~$50 cash-pay, however images may provide limited view of retina and disease pathology[3]

Nyxol's MOA Uniquely Suited As A Reversal Drop For Dilations

Source
1. Optician (2012)-Mydriatic Drugs: Practical Considerations
2. Pilocarpine FDA Label (2017)
3. Optos plc Pricing

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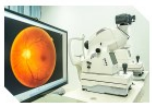
RM

Bottom-Up Calculation of Annual Dilated Eye Exams

~100 M Annual Dilated Eye Exams are Performed in the US

Demand Side Validation

	Number of Providers (X)	Average Number of Weekly Exams (Y)	Estimated % Patients Dilated (Z)	Total (X*Y*Z) * 48 wk/yr
 Optometrists	46,000	59	40%	~52 M
 Ophthalmologists	18,000	88	50%	~38 M
 Retina Specialists	3,000	150	50%	~10 M

100M
Annual Dilated Eye Exams

Supply Side Validation: Based on the ~2 million total units of mydriatic agents sold in 2020, we calculated the total number of dilated eye exams to be ~125 million patients, consistent with demand side estimates.

*IQVIA 2020 sales data; KOL Interview; GlobalData market research; and AOA Excel and Jobson Medical Information
'Bottom-Up Calculation' assumes 48 total work weeks in a year
Supply side validation assumed each unit (bottle) has ~10 mL fill volume and each patient gets 2-4 drops

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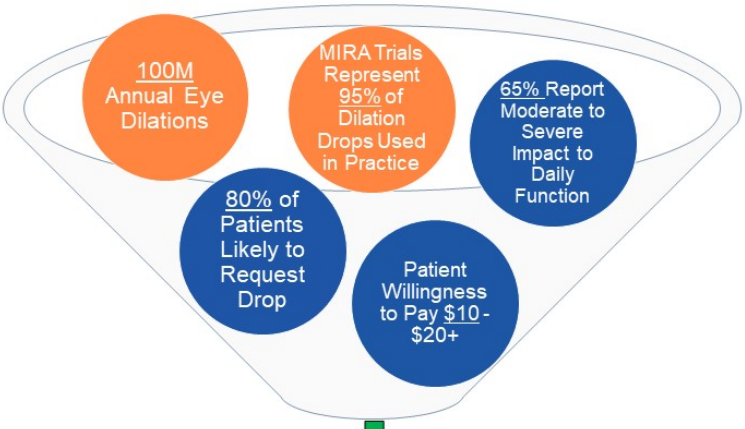
RM

Reversal of Mydriasis (RM) Market Opportunity

With No Commercially Available Treatment, Nyxol May Achieve Significant Revenue Potential

GlobalData Market Research Findings



~$500+M
Estimated US RM Market Opportunity

58%
physicians would start prescribing Nyxol within 1st year

0
Current Commercially Available Treatments

81%
patients would be more likely to schedule yearly eye exams with a reversal drop

68%
physicians would be willing to use Nyxol even if patients had to still wear sunglasses within 1st hour

Source: GlobalData Market Research Survey
Calculation: 100M Annual Eye Dilations X 65% X 80% X $10 per patient = $500+M Opportunity

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RM

More Efficient Launch Opportunity for Nyxol in RM

Launch is Poised to be Disruptive, Cost-Effective and Not Payor-Driven

Traditional Ophthalmic Launch	Ocuphire's Nyxol RM Launch
✗ Highly competitive markets (e.g., dry eye, glaucoma, allergy); little differentiation	✓ No competition or approved reversal drop → potential for Nyxol to be the only safe option
✗ Launch success takes time given payor (reimbursement) dependence	✓ Cash pay (no reimbursement barriers) allowing for quicker adoption
✗ Significant prior authorization & step-edits hurdles with burden to the practices	✓ Offering a significant value proposition to patients and practices
✗ Lengthy sales cycles and touchpoints due to chronic use and market access upkeep	✓ Shortened sales-cycle with acute use product
✗ Significant product education requirement	✓ No training given dilations routine in practices
✗ Complex distribution channel including specialty and retail pharmacies	✓ No specialty/retail pharmacy → direct to physician
✗ "**One product, one indication**" commercial model is inefficient with fixed cost infrastructure	✓ **"One product, several indications"** offers efficiencies in commercial operations

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RM

Pre-Commercial 2022 & Go-To-Market Strategy 2023

Activities Underway to Support Capital-Efficient Nyxol RM Commercial Launch

Pre-Commercial Activity

- Market Development (KOLs)
- Physician Targeting
- Patient Journey
- Brand Awareness

Go-To-Market Strategy

Potential Options for Commercialization

Work with strategic or channel partner with existing commercial ophthalmic products

Hire contract commercial organization

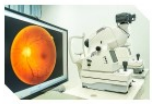
Build own salesforce

Components of an Efficient Launch

Landscape
No approved drug/competition; data-mining for high volume practices

Easy Adoption
Dilations are a routine part of practice; adoption requires no staff or patient training

Direct to Physicians
No need for pharmacy; no reimbursement, private pay



Retina
3,000 Retinal Specialists

Ophthalmology
20,000 Ophthalmologists

Optometry
46,000 Optometrists

Sources: ASRS; AMA; AAO; Women in Optometry (WO); AOA Excel and Jobson Medical Information; Physician Interviews Conducted by Ocuphire; GlobalData market research

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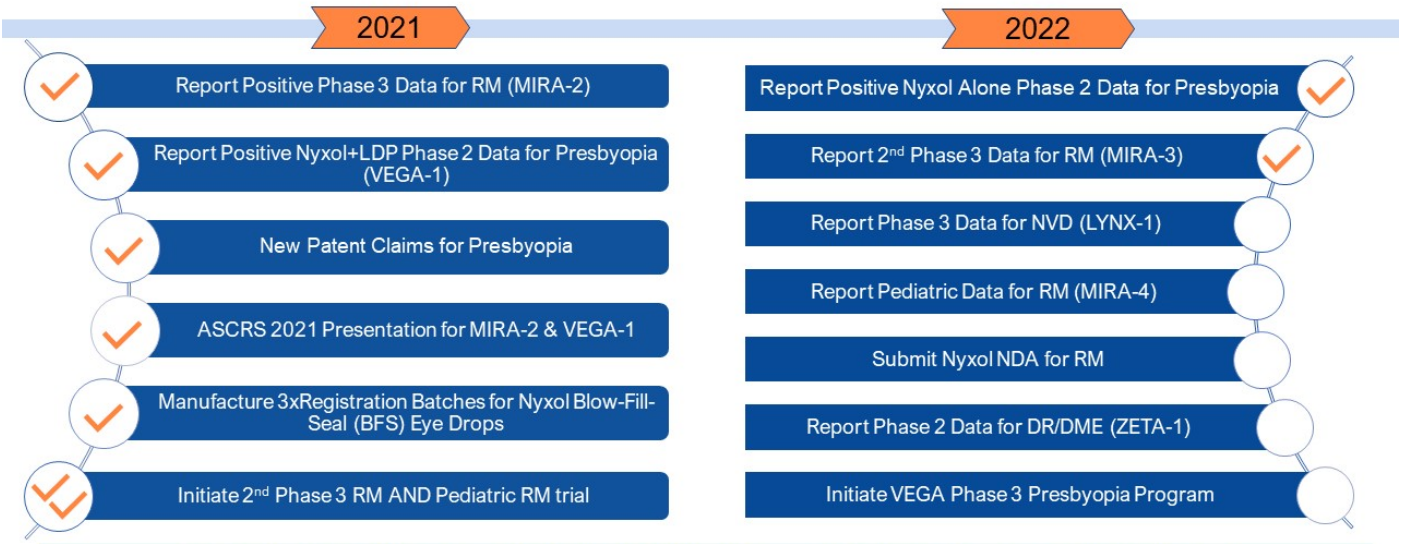
Upcoming Milestones

Track Record of Achieving Milestones ➔ Exciting 2022 News Cadence

Multiple Late-Stage Data Catalysts Expected in 2022 for Potential First NDA Approval in 2023



Ongoing Partnering Discussions with Leading Ophthalmic Companies (including European and Asian Players)

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Exhibit 99.2

Ocuphire Announces Positive Topline Results from MIRA-3 Phase 3 FDA Registration Trial for Nyxol® in the Reversal of Mydriasis

Meets Primary Endpoint With 58% Of Nyxol treated Subjects Returning to Baseline Pupil Diameter at 90 Minutes Compared to 6% of Placebo Subjects (p<0.0001)

MIRA-3 Confirms Prior MIRA-2 Phase 3 Registration Trial Showing Substantial Benefit in Accelerating Reversal of Mydriasis (RM)

NDA Filing for Nyxol in RM Planned for Late 2022

Potential Launch as Only Dilation Reversal Drop in 2H 2023

Conference Call and Webcast Today at 8.30am ET

FARMINGTON HILLS, Mich., March 29, 2022 - Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of refractive and retinal eye disorders, today announced positive topline results in the MIRA-3 trial, the company's second Phase 3 registration trial investigating its product candidate Nyxol® for the reversal of pharmacologically-induced mydriasis (dilation of pupil). Ocuphire announced positive results from its first Phase 3 trial, MIRA-2, in March 2021.

Nyxol is a proprietary, preservative-free, stable, investigational eye drop formulation of phentolamine mesylate designed to reduce pupil size by inhibiting contraction of the iris dilator muscle. MIRA-3 was designed as a multi-center, randomized, parallel arm, double-masked, placebo-controlled Phase 3 trial evaluating the safety and efficacy of Nyxol in subjects with pharmacologically-induced mydriasis. MIRA-3 enrolled 368 subjects from November 2021 to February 2022 at 16 sites in the U.S.

These topline results demonstrated that the MIRA-3 trial met its primary endpoint with 58% of subjects (study eye) treated with Nyxol returning to ≤ 0.2 mm of their baseline pupil diameter (PD) at 90 minutes compared to only 6% of subjects (study eye) treated with placebo ($p < 0.0001$). The effect was also significant at 60 minutes (Nyxol 42% vs. placebo 2%, $p < 0.0001$). In comparison, only 36% of placebo treated subjects returned back to baseline PD at 6 hours. These results showed clinically meaningful differences between Nyxol and placebo for accelerating reversal of pharmacologically-induced mydriasis.

“The successful completion of the MIRA-3 Phase 3 trial is a major milestone in our development program for Nyxol in RM,” said Mina Sooch, MBA, President and CEO of Ocuphire Pharma. “We are delighted with the positive efficacy and safety outcomes which confirm the results from our prior MIRA-2 Phase 3 trial. We now have over 900 subjects studied across 10 clinical trials of which over 550 have been exposed to Nyxol. Importantly, today’s announcement means that that we have two FDA registration trials to support potential approval for the RM indication. We intend to file an NDA with the U.S. FDA in late 2022, which, if approved, would position Ocuphire for commercial launch of Nyxol in RM in the second half of 2023. We want to thank the study participants, physicians, study site personnel, and everyone who was involved in the MIRA-2 and MIRA-3 trials for their contribution in advancing this program and bringing us closer to potentially delivering an FDA-approved treatment for RM.”

Highlights of MIRA-3 Efficacy and Safety Results

MIRA-3 (NCT05134974) is a Phase 3 registration trial evaluating the product candidate Nyxol to expedite the reversal of pharmacologically induced mydriasis. In the trial 368 study participants (336 adults and 32 adolescents at or over age 12) were randomized 2:1 to receive Nyxol (0.75% phentolamine ophthalmic solution) or vehicle control (placebo) 1 hour after receiving one of 3 mydriatic agents. The three mydriatic agents used in this trial were phenylephrine 2.5% (alpha 1 agonist targeting the iris dilator muscle), tropicamide 1% (cholinergic blocker targeting the iris sphincter muscle), and Paremyd® (a combination of hydroxyamphetamine hydrobromide 1% and tropicamide 0.25%), which are all commonly used in optometry and ophthalmology offices to dilate patients’ pupils for annual or special exams as well as surgical procedures. The study population was comprised of subjects in the modified Intent to Treat population (mITT).

Summary of MIRA-3 Topline Data

- The primary endpoint was met with 58% of subjects (study eye) treated with Nyxol returning to ≤ 0.2 mm of their baseline pupil diameter at 90 minutes compared to only 6% of placebo treated subjects ($p < 0.0001$) across the three mydriatic agents.
- Key secondary efficacy endpoints also met statistical significance:
    - Early onset of action with 42% of subjects at baseline PD by 60 minutes post-dose (vs. 2% placebo, $p<0.001$)
    - Significantly more Nyxol-treated subjects returned to normal PD or smaller than placebo-treated subjects at all time points from 1 hour to 24 hours
    - Similar efficacy was seen with one or two drops of Nyxol (as the study eye was treated with 2 drops and the fellow eye with one)
    - Nyxol was effective regardless of iris color or mydriatic agent used
    - Approximately 4 hours were gained in time to return to normal pupil diameter overall and across mydriatic agents and iris colors

- Nyxol restored normal distance corrected near vision significantly faster than placebo

- Nyxol demonstrated a favorable safety and tolerability profile.
  - Nyxol was well tolerated with no serious adverse events or withdrawals due to adverse events
  - The only AE occurring in greater than 5% subjects was mild, transient conjunctival hyperemia (11%)

Jay S. Pepose, MD, PhD, Director of the Pepose Vision Institute, Professor of Clinical Ophthalmology at Washington University School of Medicine, and Ocuphire Medical Advisory Board member and Board member commented, “Nyxol's unique MOA makes it an ideal agent for reversal of mydriasis, as it does not have the potential safety risks of retinal tears, accommodative spasm and angle closure associated with cholinergic agents like pilocarpine. The MIRA-3 and MIRA-2 trials confirm the favorable safety profile and efficacy, showing rapid reversal of mydriasis following dilation with all mydriatic agents tested and in both light and dark iris colors. In addition, the pupil reduction of 1 to 1.5 mm from baseline through 24 hours is a potential read through for our other clinical indications for Nyxol including presbyopia and night vision disturbances.”

Edward Holland, MD, Director of Cornea Services at Cincinnati Eye Institute and Ocuphire Medical Advisory Board member commented, “Pupil dilation is a necessary tool for ophthalmologists and optometrists to screen for and monitor diseases of the eye. However, patients often find dilation problematic, citing unwanted symptoms including inability to read, photophobia, loss of accommodation, and inability to work effectively. Many patients complain about or refuse dilation for these reasons. There are no approved treatments currently available for reversal of mydriasis, and with the announcement today of positive results from MIRA-3, I am very pleased to see the continued progress in advancing Nyxol toward potential FDA approval. If approved, I believe that Nyxol would be widely used in clinical practice, which could increase the overall number of dilated exams as well as improve patient experience, and lead to better eye health for our patients.”

For more information about the MIRA-3 Phase 3 trial design, please visit www.clinicaltrials.gov (NCT05134974). Ocuphire collaborated closely with Oculos Development Services, a Rush, NY based clinical research organization and subsidiary of Iuvo BioScience, on the execution of the MIRA-3 trial.

Nyxol Development Plan and Next Steps in RM

Ocuphire recently completed enrollment of 23 pediatric subjects in the MIRA-4 trial evaluating the safety and efficacy of Nyxol eye drops to reverse pharmacologically-induced mydriasis. Top line results are expected in the second quarter of 2022. If MIRA-4 meets its endpoints, the results would potentially support a broader label for Nyxol in RM to include children as young as age 3. Ocuphire is also on track to complete the Chemistry, Manufacturing and Controls (CMC) section of the NDA as three registration batches of Nyxol have been completed and on stability. The company plans to file an NDA that includes the results of MIRA-1, MIRA-2, MIRA-3, and MIRA-4 with the U.S. FDA in late 2022.

Reversal of Mydriasis Market Opportunity

Every year in the U.S., an estimated 100 million eyes dilations are conducted to examine the back of the eye, either for routine check-ups, disease monitoring or surgical procedures, across all eye care practice groups. Depending on the individual and the color of their eyes, the pharmacologically-induced dilation can last anywhere from 6 to 24 hours. Dilated eyes have heightened sensitivity to light and a decreased ability to focus on near objects, causing difficulty reading, working, and driving. Currently, there are no approved or available options to safely reverse mydriasis. Nyxol has the potential to be the first and only FDA-approved agent for RM.

Market research conducted by GlobalData surveyed several hundred patients and eye care providers (optometrists and ophthalmologists) about Reversal of Mydriasis. Over 65% of surveyed patients reported moderate to severe negative impact of a dilated pupil. These data underscore the potential value of the role of the investigational product candidate Nyxol in improving comfort and daily function after pupil dilation. Furthermore, approximately 80% of patients responded that they would be likely to request a dilation reversal drop, and more than 70% of eye care providers would be likely to use a reversal drop. The market research confirmed patients' willingness to pay out-of-pocket to reverse their dilations, supporting a market size estimate of over $500M. Ocuphire is currently evaluating partnering options for an effective and cost-efficient commercial launch of Nyxol targeted for the second half of 2023.

Conference Call and Webcast (with slides)

A more detailed presentation of the topline MIRA-3 results will be discussed on a conference call and webcast at 8.30am EDT this morning and will be posted shortly thereafter to the Investors section of Ocuphire's corporate website under the Events heading, where it will be archived and available for 90 days.

Details for the call are as follows:

Toll free:	1-877-407-4018
International:	1-201-689-8472
Conference ID:	13728061
Webcast:	Link

About Ocuphire Pharma

Ocuphire is a publicly-traded (NASDAQ: OCUP), clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders. Ocuphire's pipeline currently includes two small-molecule product candidates targeting refractive and retinal indications. The company's lead product candidate, Nyxol® eye drops (0.75% phentolamine ophthalmic solution) is a once-daily, preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size, and is being developed for several indications, including reversal of pharmacologically-induced mydriasis (RM), presbyopia and dim light or night vision disturbances (NVD), and has been studied in 10 completed clinical trials. Ocuphire has reported positive topline data from MIRA-2 and MIRA-3, two registration trials for the treatment of RM, and recently completed enrollment in a pediatric safety trial (MIRA-4) in RM. Ocuphire also reported positive top-line data from a Phase 2 trial of Nyxol for treatment of presbyopia, both Nyxol as a single agent and Nyxol with low-dose pilocarpine ("LDP") 0.4% as adjunctive therapy. The company recently completed enrollment in its Phase 3 study of Nyxol for NVD (LYNX-1). Ocuphire's second product candidate, APX3330, is an oral tablet designed to inhibit angiogenesis and inflammation pathways relevant to retinal and choroidal vascular diseases, such as diabetic retinopathy (DR) and diabetic macular edema (DME) and has been studied in 11 Phase 1 and 2 trials. The company recently announced the completion of enrollment in a Phase 2b clinical trial of APX3330 to treat DR/DME (ZETA-1). Please visit www.clinicaltrials.gov to learn more about Ocuphire's Phase 3 registration trial in RM discussed herein (NCT05134974), pediatric safety study in RM (NCT05223478), Phase 3 registration trial in NVD (NCT04638660), and Phase 2b trial in DR/DME (NCT04692688). Ocuphire previously completed the first Phase 3 registration trial in RM (NCT04620213) and Phase 2 trial in presbyopia (NCT04675151). As part of its strategy, Ocuphire will continue to explore opportunities to acquire additional ophthalmic assets and to seek strategic partners for late-stage development, regulatory preparation, and commercialization of drugs in key global markets. For more information, visit www.ocuphire.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 . Such statements include, but are not limited to, timing and results in RM, presbyopia, NVD and DR/DME future clinical trials, potential market size of RM, as well as statements concerning the success and timing of planned regulatory filings and commercialization. These forward-looking statements are based upon Ocuphire's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) the effects of COVID-19 on clinical programs and business operations, (ix) the success and timing of commercialization of any of Ocuphire's product candidates and (x) the maintenance of Ocuphire's intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Ocuphire from time to time with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Ocuphire undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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