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 15, 2021

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.)

3700 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 (Sec.230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Sec.240.12b-2 of this chapter). ☐

Item 7.01 Regulation FD Disclosure.

On March 15, 2021, Ocuphire Pharma, Inc. (the "Company") posted on its website an informational presentation regarding the results of its MIRA-2 Phase 3 registration trial for the 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 15, 2021, the Company issued a press release regarding the results of its MIRA-2 Phase 3 registration trial for the 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 15, 2021.
99.2	Press Release, dated March 15, 2021.

SIGNATURE

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 15, 2021

Exhibit 99.1

Ocuphire PHARMA

Restore Vision & Clarity

MIRA-2 Phase 3 Trial Results Conference Call

March 15, 2021

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 Ocuphire Pharma, Inc.'s ("Ocuphire" or the "Company") product candidates and potential. 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) timing or ability for the company to achieve its targeted milestones; (ii) the success and timing of regulatory submissions and pre-clinical and clinical trials; (iii) regulatory requirements or developments; (iv) changes to clinical trial designs and regulatory pathways; (v) changes in capital resource requirements; (vi) risks related to the inability of the Company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vii) legislative, regulatory, political and economic developments, and (viii) the effects of COVID-19 on clinical programs and business operations. 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.

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Agenda and Participants

First Phase 3 Trial Topline Readout as Planned in 1Q21

- Topline MIRA-2 Phase 3 Clinical Trial Results for Nyxol in Reversal of Mydriasis
- Reversal of Mydriasis Market Opportunity
- Future Milestones
- Q&A

Participants

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

Ocuphire Pipeline & Upcoming Milestones

Multiple Phase 3 & Phase 2 Clinical Data Readouts Anticipated Over the Next Year

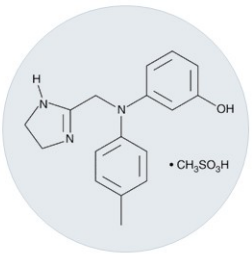
	Product Candidate	Indication	Development Stage				Anticipated Milestones
			Pre-clinical	Phase 1	Phase 2	Phase 3	
Ocuphire-Focused Development	0.75% Nyxol® Eye Drop	Dim Light or Night Vision Disturbances (NVD)	→	→	→	→	Initiated Phase 3 LYNX-1 trial 4Q2020; Data expected in 3Q21 (n=160)
	0.75% Nyxol® Eye Drop	Reversal of Mydriasis (RM)	Enrollment Complete/Data Readout				Initiated Phase 3 MIRA-2 trial 4Q2020; Topline data reported in 1Q21 (n=185)
	0.75% Nyxol® + Low-Dose 0.4% Pilocarpine Eye Drops	Presbyopia (P)	→	→	→		Initiated Phase 2 VEGA-1 trial 1Q2021; Data expected in 2Q21 (n=152)
	APX3330 Oral Pill	Diabetic Retinopathy (DR)/ Macular Edema (DME)	→	→	→		Initiate Phase 2 ZETA-1 trial 1Q2021; Data expected by early 2022 (n=100)
Partnering-Focused Development	APX2009 Intravitreal	DME, Wet Age-Related Macular Degeneration (wAMD)	→				Next steps: IND enabling studies (with partner funding)
	Combo (0.75% Nyxol® + Latanoprost) Eye Drops	Glaucoma (16 to 24 mmHg)	→	→	→		Next steps: 2nd line add-on Phase 2 trial (with partner funding)

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

Ocuphire

Nyxol®

- **NVD** Night Vision Disturbances
- **RM** Reversal of Mydriasis
- **P** Presbyopia



Phentolamine Mesylate

Topline MIRA-2 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

Objectives and Key Eligibility Criteria

MIRA-2 (OPI-NYX-RM-301) Phase 3 Trial Evaluating Reversal of Mydriasis with Nyxol or Placebo

Key Objectives

PRIMARY

- To evaluate the efficacy of Nyxol to expedite the reversal of pharmacologically-induced mydriasis across multiple mydriatic agents

KEY SECONDARY

- To evaluate the safety of Nyxol
- To evaluate multiple secondary endpoints for the reversal of pharmacologically-induced mydriasis across mydriatic agents and iris color

Key Eligibility Criteria

- Inclusion
  - Healthy ≥ 12 years of age
- Exclusion
  - Clinically significant ocular disease
  - Ocular trauma, ocular surgery or non-refractive laser treatment within the 6 months prior to screening.
  - Use of any topical prescription or over-the-counter (OTC) ophthalmic medications of any kind within 7 days of screening
  - Recent or current evidence of ocular infection or inflammation in either eye
  - History of any traumatic (surgical or nonsurgical) or non-traumatic condition affecting the pupil or iris

Clinical trial NCT#04620213

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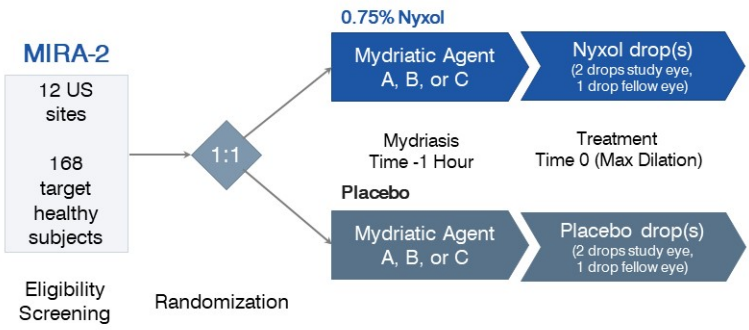
RM MIRA-2 Phase 3 Registration Design

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



Started and Completed Enrollment in 4Q20 – 185 Subjects

Topline Results Expected in 1Q21 – Reported on 3/15/21

Endpoints

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

Secondary:

- % of subjects returning to baseline at 30min, 1h, 2h, 3h, 4h, 6h, 24h (overall, by mydriatic agent, by iris color)
- Mean change in pupil diameter from mydriatic max at all timepoints (overall, by mydriatic agent, by iris color)
- Accommodation (Tropicamide/Paremyd)
- Safety and tolerability (redness)

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

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Demographics (mITT Population)

Treatment and Placebo Arms Were Balanced in this Phase 3 Registration Trial

	Nyxol n=94	Placebo n=91	Total n=185
Demographics			
Age (years): Median (Range)	31 (12-70)	30 (13-73)	31 (12-73)
Sex: Male n (%) **Female** n (%)	36 (38%) 58 (62%)	36 (40%) 55 (60%)	72 (39%) 113 (61%)
Race: White n (%) **African American** n (%) **Asian** n (%) **Other ^** n (%) *^ includes American Indian or Alaska Native; Native Hawaiian or Other Pacific Islander*	70 (75%) 17 (18%) 6 (6%) 2 (2%)	74 (81%) 16 (18%) 3 (3%) 1 (1%)	144 (78%) 33 (18%) 9 (5%) 3 (2%)
Dark Iris Color: n (%)	49 (52%)	46 (51%)	95 (51%)
Light Iris Color: n (%)	45 (48%)	45 (50%)	90 (49%)

Note: 14 pediatric subjects 12-17years old were enrolled in the trial; Race is more than 100% given subjects could check more than one category.

Source: MIRA-2 TLR table #14.1.2.3 modified Intent To Treat (mITT)

Baseline Characteristics Study Eye (mITT Population)

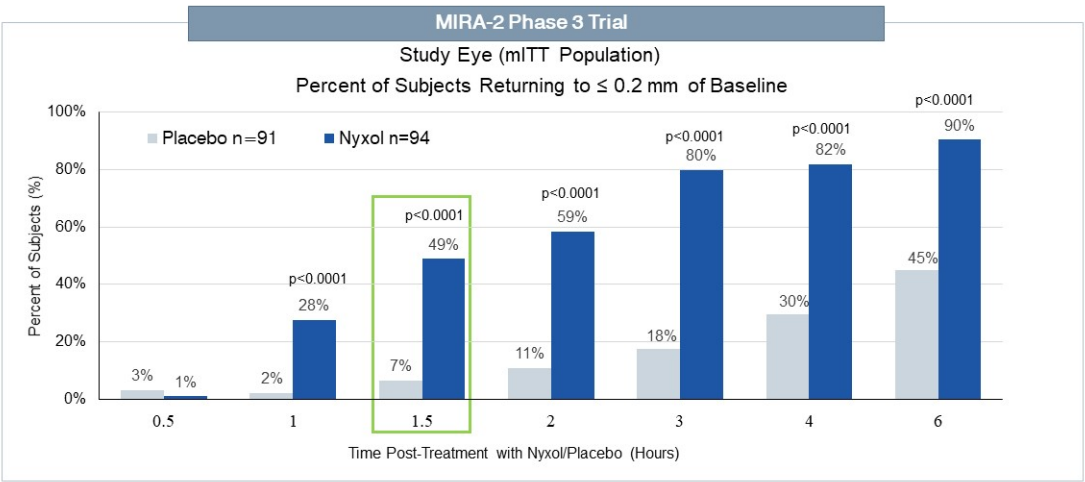
Treatment and Placebo Arms Were Balanced Across These Ocular Measurements

	Nyxol n=94	Placebo n=91	Total n=185
Baseline Characteristic			
Baseline Pupil Diameter Mean (mm)	5.09	5.18	5.13
Max Dilated Pupil Diameter Mean (mm)	7.21	7.20	7.20
Accommodation Median (diopters)	7.28	7.41	7.41
BCDVA letters *55 letters = 20/20*	57	59	58
DCNVA letters *70 letters = 20/20*	58	61	59
IOP (mmHg)	15.3	15.1	15.2

Source: MIRA-2 TLR table #14.1.2.3 (mITT)

Primary Endpoint: % of Subjects Study Eye Returning to Baseline PD at 90 Min

Nyxol Met the Primary Endpoint at 90 Min; Additionally at 60 Min and All Subsequent Timepoints



Source: MIRA-2 TLR table #14.2.1.1 (mITT). Data include all three mydriatics (Phenylephrine, Tropicamide, Paremyd)

Secondary Endpoint: % of Subjects Returning to Baseline PD by Mydriatic Agent

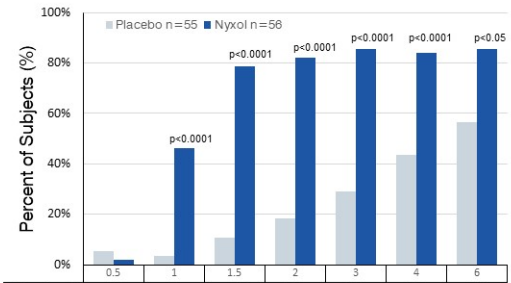
Subjects Dilated with Phenylephrine had a Faster Response to Nyxol than Tropicamide/Paremyd

MIRA-2 Phase 3 Trial

Study Eye (mITT Population)

Percent of Subjects Returning to ≤ 0.2 mm of Baseline by Mydriatic Agent

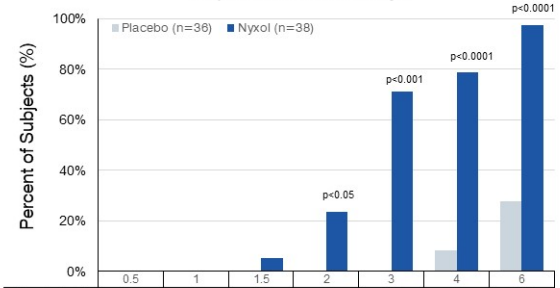
Phenylephrine



	0.5	1	1.5	2	3	4	6
Placebo n=55	6%	4%	11%	18%	29%	44%	56%
Nyxol n=56	2%	46%	79%	82%	86%	84%	86%

Time Post-Treatment with Nyxol/Placebo (Hours)

Tropicamide or Paremyd



	0.5	1	1.5	2	3	4	6
Placebo (n=36)	0%	0%	0%	0%	0%	8%	28%
Nyxol (n=38)	0%	0%	5%	24%	71%	79%	97%

Time Post-Treatment with Nyxol/Placebo (Hours)

Source: MIRA-2 TLR table #14.2.1.4 (mITT)

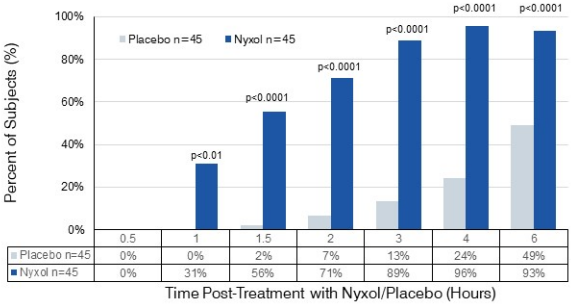
Secondary Endpoint: % of Subjects Returning to Baseline PD by Iris Color

Evidence of Efficacy in Subjects with Both Light and Dark Irides, with a More Vigorous Response in Light Irides

MIRA-2 Phase 3 Trial

Study Eye (mITT Population)
Percent of Subjects Returning to ≤ 0.2 mm of Baseline by Iris Color

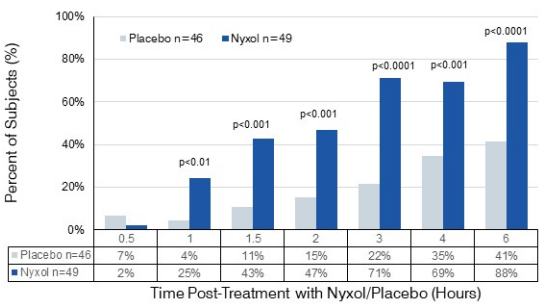
Light Irides



	0.5	1	1.5	2	3	4	6
Placebo n=45	0%	0%	2%	7%	13%	24%	49%
Nyxol n=45	0%	31%	56%	71%	89%	96%	93%

Time Post-Treatment with Nyxol/Placebo (Hours)

Dark Irides



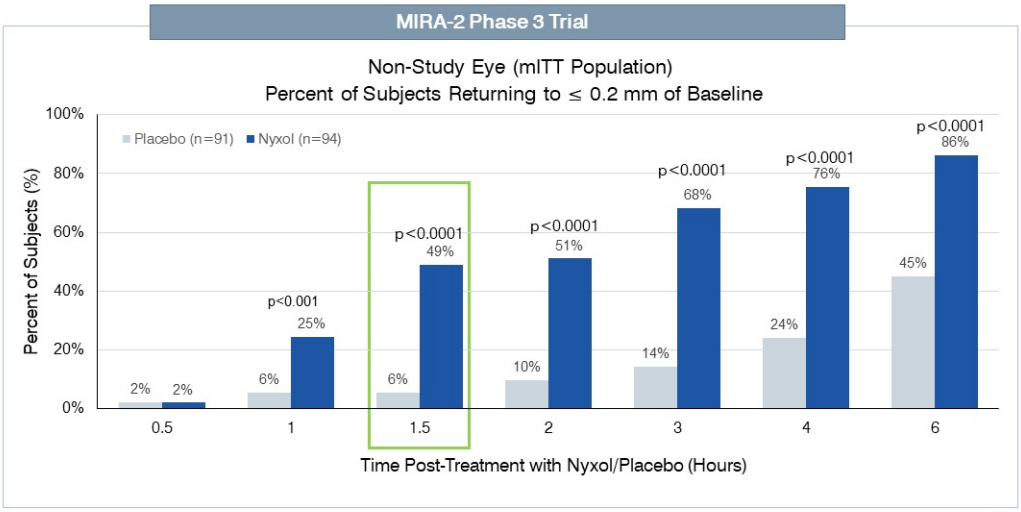
	0.5	1	1.5	2	3	4	6
Placebo n=46	7%	4%	11%	15%	22%	35%	41%
Nyxol n=49	2%	25%	43%	47%	71%	69%	88%

Time Post-Treatment with Nyxol/Placebo (Hours)

Source: MIRA-2 TLR table #14.2.1.6 (mITT). Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd)

Secondary Endpoint: % of Subjects Non-Study Eye Returning to Baseline PD

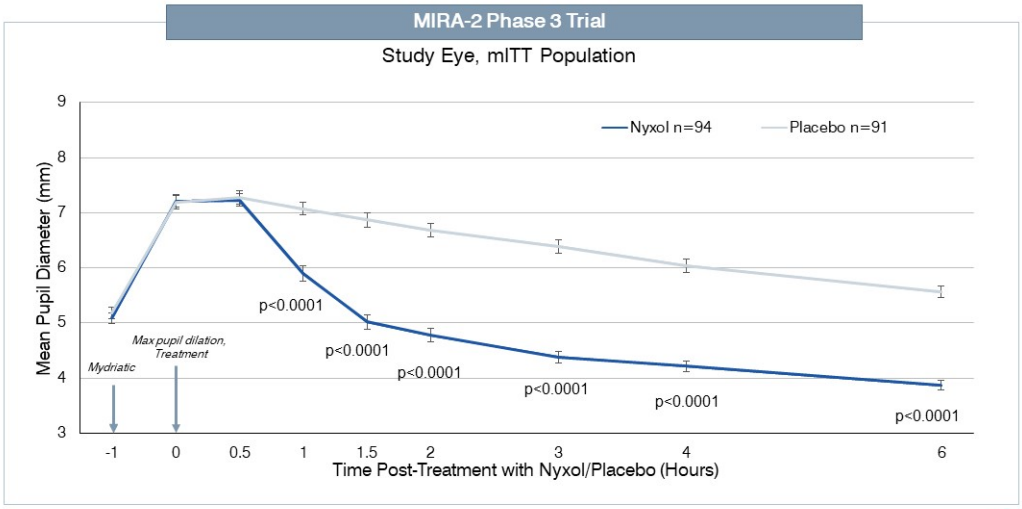
A Similar Significant Effect was Obtained with a Single Drop of Nyxol in the Non-Study Eye



Source: MIRA-2 TLR table 14.2.1.2 (mITT). Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd)

Secondary Endpoint: Mean Pupil Diameter Over Time

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



Source: MIRA-2 TLR table #14.2.2.1 (mITT). Standard Error bars are shown. Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd)

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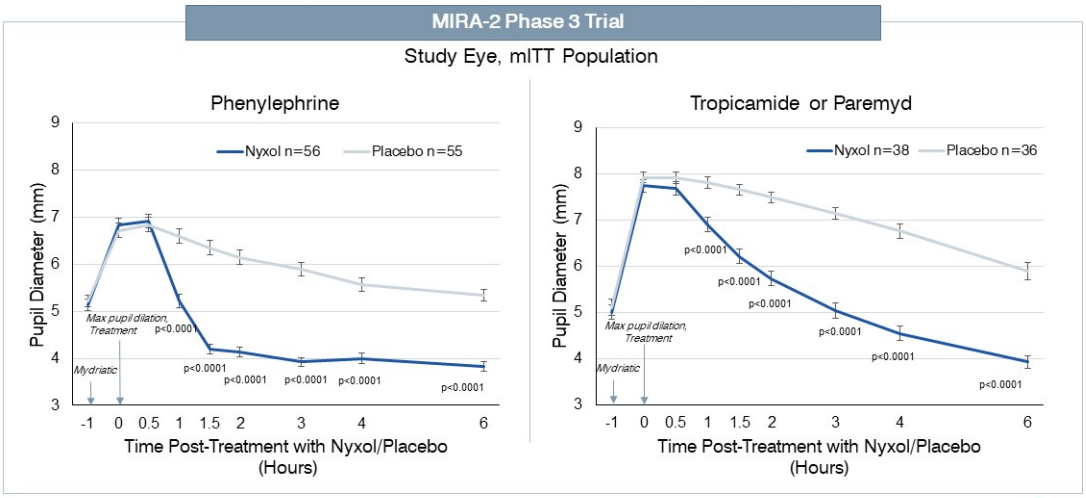
Secondary Endpoint: Mean Pupil Diameter Over Time by Mydriatic Agent

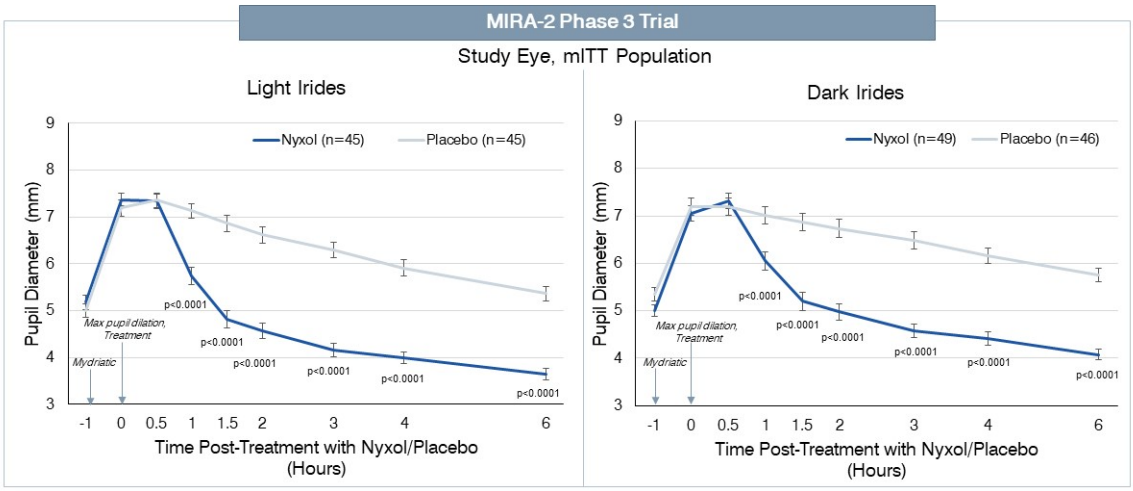
Nyxol Reduced Pupil Diameter With All Mydriatic Agents; More Rapidly with Phenylephrine as Expected



Source: MIRA-2 TLR table #14.2.2.3 (mITT). Standard Error bars are shown.

Secondary Endpoint: Mean Pupil Diameter Over Time by Eye Color

Nyxol Reduced Pupil Diameter More Rapidly in Both and Light Dark Irides

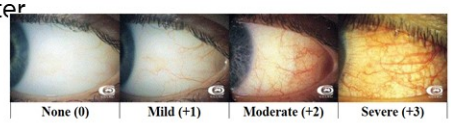


Source MIRA-2 TLR table #14.2.1.5. Standard Error bars are shown. Data includes all three mydriatics (Phenylephrine, Tropicamide, Paremyd)

Secondary Endpoint: Safety Findings

Nyxol was Well Tolerated with a Favorable Safety Profile

- There were no deaths, serious AEs, or withdrawals due to AEs
- Only AEs, occurring in ≥ 5% of subjects treated with Nyxol, were instillation site discomfort (38% Nyxol vs. 9% placebo) and conjunctival hyperemia (13% Nyxol vs. 0% placebo)
  - 94% of the AEs in the Nyxol group were mild
- Conjunctival hyperemia was observed to be mild and transient
  - From a baseline mean of 0.7, the mean hyperemia score increased by approximately 1.0 unit (on a 4-point scale) at 60 minutes post-dose and decreased steadily thereafter



- Visual acuity was not adversely affected by Nyxol

Source MIRA-2 Safety Population TLR table 14.3.1.1.; MIRA-2 table 14.3.1.2.2 System Organ Class; MIRA-2 table 14.3.3.2 Hyperemia Score by Time Point

Summary of Positive MIRA-2 Phase 3 Results for Nyxol Eye Drops

Sustained Efficacy with a Favorable Safety Profile in Reversing Mydriasis with Nyxol

- **Met primary endpoint at 90 minutes with high statistical significance with 2 drops of Nyxol**
- **Met all key secondary endpoints with high statistical significance**
  1. Efficacy for all 3 mydriatic agents – phenylephrine, tropicamide, and ~~p~~Paremyd®
  2. Efficacy in both light and dark iris colors
  3. Efficacy with only one Nyxol drop in non-study eye
- **Favorable safety profile**
  - Mild, transient conjunctival hyperemia reported in the first hour and declined steadily thereafter
  - No serious AEs, no drop-outs from AEs, no systemic AEs were observed in ≥ 5% of subjects
- **Validates Nyxol mechanism of action, therapeutic effect, and safety profile in the other two indications of presbyopia and night vision disturbances**

Next Steps For Nyxol RM Indication for NDA

NDA Submission Expected Early 2023

- Perform a second Phase 3 RM registration trial (MIRA-3)
  - Planned 330 subjects randomized 2:1 to Nyxol or Placebo
    - In addition to confirming efficacy, this trial will satisfy the regulatory requirement for number of subjects (300 or more) exposed for approval for acute use (24 hours)
    - Limited pharmacokinetic sampling will be obtained in a small subset of subjects
  - Results anticipated 1Q2022
- Perform a small (20-30 subjects) pediatric RM trial (age 3 – 17 years) to satisfy pediatric research plan regulatory requirement
- Manufacture and complete one-year stability on three registration batches for Nyxol single unit dose Blow-Fill-Seal vials

Proposed Indication

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

Reversal of Mydriasis Market Opportunity

Nyxol Product Candidate Profile

Novel Alpha 1/2 Blocker Eye Drop for Refractive Indications (505(b)(2) Pathway)

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

Efficacy Data

Improving Vision

- ↓ Pupil Size (moderate miotic)
- ↑ Contrast Sensitivity (night)
- ↑ Near Visual Acuity (light/dark)
- ↑ Distance Visual Acuity

Safety Data

No Systemic Effects
No Changes in Blood Pressure
No Changes in Heart Rate

Tolerated Topical Effects
Mild / Transient / Reversible Eye Redness

IOP Unchanged or Decreased
↓ Intraocular Pressure (IOP) at Normal Baseline

Chronic daily dosing of Nyxol at bedtime demonstrated ***no significant daytime redness*** *and durability of effects for more than* ***24 hours***

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Reversal of Mydriasis (RM) – Acute Treatment

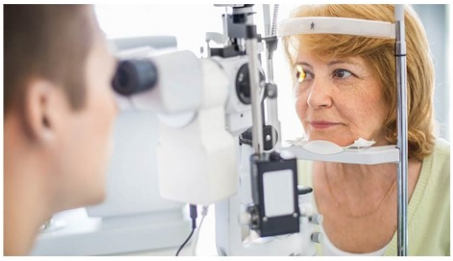
Annual Exams and Specialty Visits Involve Dilation to Monitor Eye Health

The Problem

- At many annual eye exams and specialty visits, pupils are pharmacologically dilated, impairing vision for 6-24 hours
- Dilated eyes:
  - heightened sensitivity to light
  - inability to focus
  - reading, working, and driving are difficult
  - halos and glare

> *"I have to stay indoors. They say it only lasts a few hours, but it lasts all day, and it is very annoying."*
>
> *RM Patient, Aged 51*

No Current Commercially Available Treatments



~100M eye exams / year in US

Source: GlobalData Market Research Report, 2020

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Reversal of Mydriasis (RM) – Acute Treatment

Single Use Indication Leveraging a Precedent Approval Pathway

Nyxol's Potential Differentiated Solution

- **Regulatory Precedent** with Rev-Eyes (an alpha 1 blocker), approved by the FDA in 1990 but shortly thereafter discontinued (not for safety or efficacy reasons)
- **Clinical Effect** to potentially reduce pupil size and counteract the effect of mydriatic drugs (alpha agonists and cholinergic blockers) used to dilate the pupil
- **Convenient** eye drop given at the office that may allow vision to return to normal sooner
- **Tolerable** with a minimal side effect profile (unlike cholinergic agonists such as pilocarpine)

Before

After

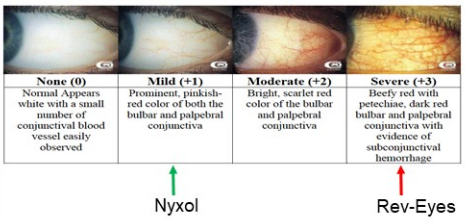
Seeking Treatment Findings	
Patients likely to request reversal of dilation	45%
Eye care providers likely to use reversal drops	40%

Source: GlobalData Market Research Report, 2020

Nyxol Comparison to Rev-Eyes

Nyxol has a Distinct Commercial Advantage to Rev-Eyes

	Nyxol	Rev-Eyes
Tolerability	• Mild hyperemia	• Severe hyperemia (80%)
Comfort	• Mild discomfort (38%), erythema (4%), or instillation pain (3%)	• Burning/Stinging (50%)
Side effects	• None reported	• 40% (ptosis - droopy eyelids)
Commercial Product Presentation	• Stable • Preservative-free • Sterile • Single-unit dose packaging • Normo-osmolar solution	• Requires aseptic technique for reconstitution and mixing at physician office • Stable for 21 days after product is reconstituted • Contains preservative • Hyperosmolar solution
No. of drops instilled	• 1-2 drops/eye	• 4 drops/eye (2 drops, followed 5 minutes later by 2 additional drops)



Source: Rev-Eyes (Dapiprazole HCL) Eyedrops 0.5% Summary Basis of Approval

Summary of RM Market Opportunity

A Substantial Revenue Opportunity for Nyxol in Reversal of Mydriasis

- ~100M comprehensive and specialty eye exams in US per year
- No current commercially available treatment for reversing dilation
  - Optomap ultra-wide field camera used for a retinal evaluation without the need for dilation; ~$40 – $65 cost to patient[1]
- Findings from recent US market research[2]:
  - Over 65% patients report moderate to severe negative impact of dilated exams
  - Cash pay price range surveyed $5-$20 per patient treatment
  - 45% patients said they would likely request a dilation reversal drop

Estimated US Market Opportunity- $325M- $1B+

- Eye exam market posted a 3.3% growth to $6.39B[3]
- Given the efficacy of Nyxol to reverse dilation regardless of eye color, there are additional markets outside of the US for potential commercialization

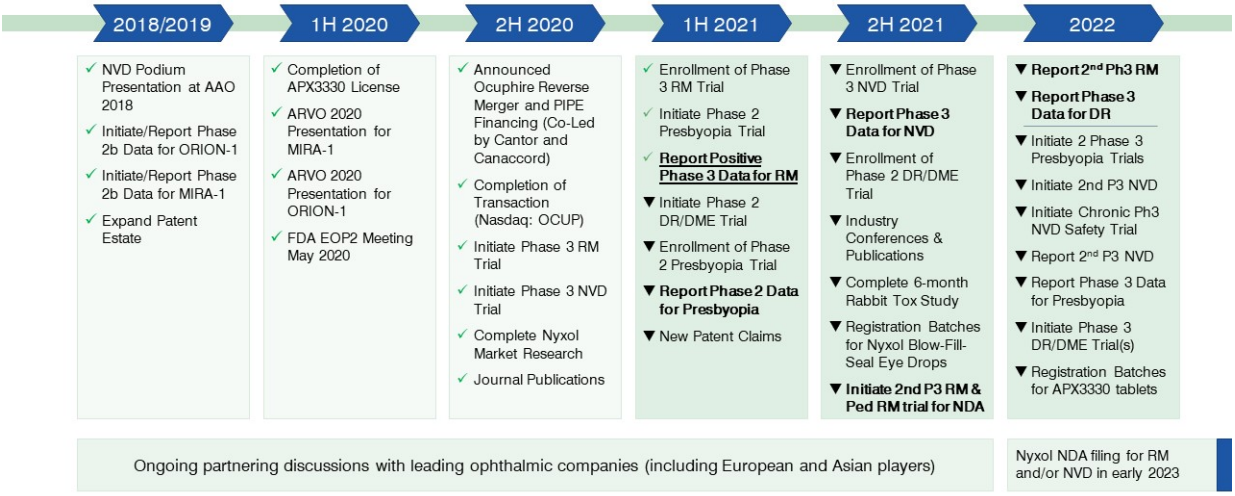
1. Corcoran Consulting Group FAQ for Optomap imaging 01/2021
2. GlobalData market research report
3. Vision Care Market Grows 2.4 Percent in 12-Months Ending September 2019. Vision Monday, January 20, 2020.

Ocuphire

Future Milestones

2021 to 2022 Ocuphire Cadence of Milestones

Multiple Data Catalysts on Path to NDA(s)



Ocuphire PHARMA

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Restore Vision & Clarity

Q&A

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Exhibit 99.2

Ocuphire Announces MIRA-2 Phase 3 Registration Trial for the Reversal of Mydriasis Meets Primary Endpoint

Nyxol Meets Its Primary and Multiple Secondary Endpoints Including Statistically Significant Efficacy Returning Subjects More Rapidly to Normal Pupil Size Across a Breadth of Dilating Agents and Iris Colors

Nyxol has Potential to be a New Treatment Option for Reversal of Pharmacologically-Induced Pupil Dilation

Conference Call and Webcast Today @ 8:30am ET

Farmington Hills, Mich., March 15, 2021 - Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders, today announced positive top line results in the MIRA-2 Phase 3 registration trial investigating its product candidate Nyxol® for reversal of pharmacologically induced mydriasis (dilation of pupil for eye exams). 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-2 was designed as a multi-center, randomized, double-masked, placebo-controlled, parallel, 24-hour Phase 3 trial that planned 168 healthy study participants, and ultimately enrolled 185 study participants.

These topline results indicate that the MIRA-2 trial met its primary endpoint with 49% percent of subjects (study eye) treated with Nyxol returning to ≤ 0.2 mm of their baseline pupil diameter at 90 minutes compared to 7% of subjects (study eye) treated with placebo ($p < 0.0001$). The study population was comprised of subjects who had received one of three mydriatic (dilating) agents in the modified Intent to Treat population (mITT). The three mydriatic agents used in this trial were phenylephrine 2.5% (alpha 1 agonist works on the iris dilator muscle), tropicamide 1% (cholinergic blocker works on 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.

"The successful outcome of this Phase 3 MIRA-2 FDA registration trial is a major milestone for Ocuphire and we are thrilled to announce these positive and clinically meaningful results. Nyxol showed a statistically significant improvement on the primary as well as multiple secondary endpoints, demonstrating its ability to more rapidly return pupil diameter back to normal baselines over multiple timepoints, breadth of iris colors, and dilating agents that work on one or both iris muscles that control pupil size," said Mina Sooch, MBA, President and CEO of Ocuphire Pharma. "These Phase 3 results build on a growing body of evidence to establish Nyxol's therapeutic product profile including the positive results seen in our recently published MIRA-1 Phase 2b trial. This further validates the mechanism of action, therapeutic effect, and safety profile of the Nyxol platform for potential additional refractive indications - presbyopia and night vision disturbance. We are very grateful to the study participants and investigators who participated in this U.S. study."

Highlights of MIRA-2 Topline Efficacy and Safety Results

MIRA-2 (NCT04620213) is a Phase 3 registration trial evaluating the product candidate Nyxol to expedite the reversal of pharmacologically induced mydriasis. In the trial 185 study participants (171 adults and 14 adolescents at or over age 12) were randomized 1:1 to receive Nyxol (0.75% phentolamine ophthalmic solution) or vehicle control (placebo) 1 hour after receiving one of 3 mydriatic agents.

- The primary endpoint was met with 49% percent of subjects (study eye) treated with Nyxol returning to ≤ 0.2 mm of their baseline pupil diameter at 90 minutes compared to 7% of placebo treated subjects ($p < 0.0001$) across three mydriatic agents (phenylephrine, tropicamide, and Paremyd®).
- Multiple secondary efficacy endpoints also met statistical significance.
    - A clinically meaningful higher number of Nyxol treated subjects (study eye and non-study eye) returned to baseline pupil diameter at 60 minutes compared to placebo, and every subsequent timepoint through 6 hours post-dosing.
    - Nyxol treated subjects had mean pupil diameters that were 1 to 2.5 mm smaller than placebo treated subjects at all timepoints from 1 to 6 hours post-dosing.
    - Nyxol treated subjects returned to baseline pupil diameter more quickly than placebo treated subjects with:
        (i) all three dilating agents;
        (ii) both light and dark irides; and
        (iii) with one and two drops of Nyxol.
- Nyxol demonstrated a favorable safety profile.
    - Nyxol was well-tolerated in the study population with no serious adverse events or withdrawals due to adverse events.
    - A mild transient increase in conjunctival hyperemia was observed in Nyxol treated subjects which peaked at one hour post-dose and decreased steadily thereafter.

Jay S. Pepose, MD, PhD, Director of the Pepose Vision Institute, Professor of Clinical Ophthalmology at the Washington University School of Medicine, and Ocuphire Medical Advisory Board member commented, “I am excited to see robust effects of Nyxol in reversing pharmacologically induced mydriasis with a favorable safety profile. The Phase 3 trial results exceeded my expectations with statistical and clinical significance on the primary endpoint at 90 minutes, as well as at the earlier 60 minute timepoint. In addition, Nyxol demonstrated significant benefit through 6 hours across the range of commonly used mydriatic agents, light and dark iris colors, and age cohorts. Nyxol is unique as the only alpha-1/2 antagonist in clinical trials. Nyxol has the potential to address an unmet medical need as there are no commercial treatments currently available for reversal of mydriasis. If approved for marketing by the FDA, Nyxol may provide substantial benefit to patients after dilation, and may even increase the compliance with standard of care guidance for dilated examinations during visits to eye care specialists and thereby improve overall eye health.”

A more detailed presentation of the topline MIRA-2 results will be discussed on a conference call this morning and posted shortly thereafter to the Investors section of Ocuphire's corporate website in the Events section. For more information about the MIRA-2 Phase 3 trial design and its 12 U.S. clinical sites, please visit www.clinicaltrials.gov (NCT04620213). Ocuphire collaborated closely with Oculos Development Services, a Tampa, Florida based clinical research organization and subsidiary of Iuvo BioScience, on the execution of the MIRA-2 trial.

Building on the positive results of this first completed Phase 3 registration trial for Nyxol (MIRA-2), a second Phase 3 registration trial (MIRA-3) is planned to initiate in the second half of this year. A New Drug Application (NDA) to obtain approval to market Nyxol for this pharmacologically induced mydriasis indication is expected to be submitted to the FDA in early 2023.

Full results from the MIRA-2 Phase 3 trial will be presented at an upcoming industry conference - 2021 ASCRS Annual Meeting July 23–27 in Las Vegas, Nevada. Ocuphire also plans to submit these Phase 3 results to a peer-reviewed journal for publication later this year.

Reversal of Mydriasis Market Opportunity

Every year in the U.S., approximately 100 million eye exams are performed that require dilation of the pupil (mydriasis) to examine the back of the eye either for routine check-ups, disease monitoring or surgical procedures. 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 an inability to focus on near objects, causing difficulty with reading, working, and driving.

Market research conducted by GlobalData surveyed several hundred patients and eye care providers (optometrists and ophthalmologists) about Reversal of Mydriasis (as well as Night Vision Disturbances and Presbyopia). Over 65% of surveyed patients reported moderate to severe negative impact of a dilated exam. This underscores the potential value of the role of the investigational product candidate Nyxol in improving comfort and daily function after pupil dilation. Additionally, an estimated 45% of patients responded that they would be very likely to request a dilation reversal drop, and more than 40% of eye care providers would be likely to use a reversal drop if such a treatment were commercially available.

Conference Call and Webcast (with slides)

Ocuphire management will host a conference call and webcast with slides, today at 8.30am ET. Details for the call are as follows:

Toll free (U.S.)	877-407-4018
International:	201-689-8471
Conference ID	13717533
Webcast:	http://public.viavid.com/index.php?id=143904

The webcast will also be available on the "Investors" tab of the Ocuphire corporate website tab, underNews & Events and will be archived for 90 days.

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 front and back of the eye indications. The company's lead product candidate, Nyxol® (0.75% phentolamine ophthalmic solution) Eye Drops, 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 dim light or night vision disturbances (NVD), reversal of pharmacologically-induced mydriasis (RM), and presbyopia, and has been studied in 8 clinical trials including the recently completed Phase 3 trial in RM. Nyxol is also currently in Phase 3 clinical development for NVD and in Phase 2 for presbyopia. 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. APX3330 is entering Phase 2 clinical development for DR/DME. 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. Please visit www.clinicaltrials.gov to learn more about Ocuphire's completed Phase 2 trials, recently completed Phase 3 registration trial (NCT04620213), ongoing Phase 3 registration trial (NCT04638660) and Phase 2 trial in presbyopia (NCT04675151), and soon to recruit Phase 2 trial in DR/DME (NCT04692688). For more information, please 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, statements concerning Ocuphire's product candidates, results of ongoing and future clinical trials, and commercialization and market opportunities. 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; (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, and (ix) the success and timing of commercialization of any of Ocuphire's product candidates. 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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