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): April 28, 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 8.01 Other Events.

On April 28, 2022, the Company issued a press release regarding the results of its MIRA-4 pediatric safety trial for reversal of mydriasis. A copy of the press release is filed as Exhibit 99.1 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	Press Release, dated April 28, 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: April 28, 2022

Ocuphire Completes Last Clinical Trial Supporting the Planned 2022 NDA Submission with the Announcement of Positive Results from MIRA-4 Pediatric Safety Trial Evaluating Nyxol® for Reversal of Mydriasis

Nyxol Demonstrated a Favorable Safety Profile and Rapidly Reversed Dilated Eyes in Pediatric Subjects 3 to 11 Years Old, Consistent with Findings in MIRA-2 and MIRA-3 Phase 3 Registration Trials

MIRA-4 Results Support Potential Broader Label for Nyxol in RM to Include Pediatrics

NDA Filing for Nyxol in RM Planned for Late 2022 with Potential Launch in 2H 2023

FARMINGTON HILLS, MI, April 28, 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 results in the MIRA-4 pediatric safety trial investigating its product candidate Nyxol® for the reversal of pharmacologically-induced mydriasis (dilation of pupil). The results demonstrated that Nyxol's efficacy and safety in pediatric subjects 3-11 years of age was consistent with that shown in previous studies conducted by Ocuphire which enrolled both adolescents (age 12-17 years) and adults (age 18 years and older), showing a rapid reversal of pharmacologically-induced mydriasis (RM) and a favorable safety profile.

Nyxol is a proprietary, preservative-free, stable, investigational eye drop formulation of phentolamine mesylate designed to uniquely modulate the pupil size by blocking the α1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. MIRA-4 is part of the comprehensive MIRA clinical program to develop Nyxol for RM. MIRA-4 enrolled 23 pediatric subjects from two sites in the U.S in two months. Ocuphire plans to submit an NDA that includes the results of MIRA-1, MIRA-2, MIRA-3, and MIRA-4 with the U.S. FDA in late 2022. The company is currently evaluating partnering and distribution options for an effective and cost-efficient commercial launch of Nyxol targeted for the second half of 2023, if approved.

"We are very pleased with the compelling safety results in young children from the MIRA-4 trial, marking the fourth positive data milestone in our Nyxol program in RM," said Mina Sooch, MBA, Founder and CEO of Ocuphire Pharma. "These results add to our large body of clinical data demonstrating the safety and efficacy of Nyxol for RM and may potentially support a broader label to include children as young as age 3 to older adults. The rapid and large magnitude of Nyxol response of 64% in the MIRA-4 trial is consistent with that seen in the MIRA-2 (49%) and MIRA-3 (58%) trials. We remain on track for our planned NDA submission to the FDA later this year, and if approved, Ocuphire will be well positioned for a launch in the second half of 2023 for Nyxol as the only commercially-available treatment option indicated for reversing pharmacological eye dilation. We thank the study participants, physicians, study site personnel, and everyone involved in the MIRA trials for their contributions in advancing this program."

Highlights of MIRA-4 Safety and Efficacy Results

MIRA-4 (NCT05223478) is a pediatric trial evaluating the safety and efficacy of Nyxol in healthy subjects with pharmacologically-induced mydriasis as agreed with the FDA under the Pediatric Research Equity Act. In the trial, 23 pediatric subjects (two age groups: 3 to 5 years and 6 to 11 years) were randomized to receive one drop of Nyxol (0.75% phentolamine ophthalmic solution) or placebo (Nyxol vehicle) 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%), all of which are commonly used in optometry and ophthalmology offices to dilate patients' pupils for annual comprehensive or special eye exams as well as surgical procedures. The primary endpoint is safety with descriptive statistics for secondary efficacy endpoints.

Summary of MIRA-4 Data

Primary Safety Endpoint(s)

- The primary endpoint was met with Nyxol demonstrating a favorable safety and tolerability profile. There were no adverse events in this pediatric trial. Specifically, no complaints of headaches, redness, instillation site discomfort or pain, blurry vision, burning or stinging were reported. There was no change in vital signs.

Key Secondary Efficacy Endpoints

- At 90 minutes post-dose, 64% of Nyxol treated subjects had returned to baseline pupil diameter (PD) compared to 25% on placebo.
- At 3 hours post-dose, 82% of Nyxol treated subjects had returned to baseline PD compared to 33% on placebo.
- At 24 hours post-dose, 91% of Nyxol treated subjects had returned to baseline PD compared to 51% on placebo.
- The mean time to return to baseline PD was reduced by ~3 hours in Nyxol treated subjects compared to placebo.
- Nyxol was effective for all 3 dilating agents used and across light and dark irides.

Chris Pearson, O.D., Sabal Eye Care, FL, an investigator in the MIRA-3 and MIRA-4 clinical trials commented, "It is now well established that there is a notable increase in the prevalence of eye disorders such as myopia and amblyopia that require a comprehensive eye exam in children, and as a result, there is now an increased need for eye exams that require pupil dilation in children. The availability of a safe and effective pharmaceutical drop that can reverse eye dilation has the potential for broad use. Having a pediatric label would mean that children, as well as adults, could benefit."

For more information about the MIRA-4 trial design, please visit www.clinicaltrials.gov (NCT05223478). 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-4 trial and overall MIRA program.

Reversal of Mydriasis Market Opportunity: Adults and Pediatrics

An estimated 100 million eye dilations are conducted every year in the U.S. 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 in adults. Dilated eyes have heightened sensitivity to light and an inability to focus on near objects, causing difficulty reading, working, and driving. Currently, there are no approved or available treatment options to safely reverse mydriasis. If approved, Nyxol has the potential to be the only FDA-approved drug for the reversal of mydriasis uniquely modulating the pupil by blocking the α1 receptors found only on the iris dilator muscle without affecting the ciliary muscle.

According to the American Association for Pediatric Ophthalmology and Strabismus, dilating eye drops can last anywhere from 4 to 24 hours in children depending on the strength, type of the drop and the individual patient. Rapidly reversing the effects of dilation can benefit multiple stakeholders including children, their parents and even teachers, facilitating the child's return to school, sports, and homework.

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 11 completed clinical trials. Ocuphire has reported positive data from MIRA-2 and MIRA-3 registration trials and MIRA-4 pediatric safety trial for the treatment of 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 trial 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 recently completed Phase 3 registration trial in RM (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, the market for RM (in adults and pediatrics), future clinical trials, as well as statements concerning the success and timing of planned regulatory filings, product label and commercialization of Ocuphire's product candidates. 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.

Ocuphire Contacts

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