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): December 6, 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 December 6, 2022, Ocuphire Pharma, Inc. (the "Company") issued a press release announcing the submission of a New Drug Application to the U.S. Food and Drug Administration for Nyxol® for the reversal of pharmacologically-induced mydriasis produced by adrenergic agonist (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents, or a combination thereof. 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 December 6, 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: December 6, 2022

Exhibit 99.1

Ocuphire Pharma Announces Submission of New Drug Application to FDA for Nyxol® Eye Drops for Reversal of Mydriasis

NDA Supported by Positive Phase 3 Data Demonstrating Rapid Reversal of Dilated Eyes and Favorable Safety Profile in Pediatric and Adult Subjects

FARMINGTON HILLS, Mich., December 6, 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 the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Phentolamine Ophthalmic Solution 0.75% (Nyxol®) for the reversal of pharmacologically-induced mydriasis (RM) produced by adrenergic agonist (e.g., phenylephrine) or parasympatholytic (e.g., tropicamide) agents, or a combination thereof.

"The NDA submission for Nyxol is an important step toward our goal of providing a reversal option for the millions of standard eye exams and procedures that involve dilation," said Mina Sooch, MBA, Founder and CEO of Ocuphire Pharma. "Achieving this milestone is a testament to the commitment of the clinical trial investigators, their staff and trial participants as well as the Ocuphire team and its network of development partners who have worked diligently to advance Nyxol towards a potential approval in RM. We look forward to working closely with the FDA during the review process. If approved, Nyxol is expected to be the only commercially available treatment option indicated for the reversal of dilated eyes. We are excited to add this important milestone to our recently closed global license agreement with FamyGen Life Sciences (Famy) for the development and commercialization of Nyxol across three indications. With the separately announced acquisition of Famy by Viatris (Nasdaq: VTRS), a global healthcare company, we believe Viatris provides a great opportunity for all of the Nyxol indications to realize their full commercial potential in their respective markets given its strategic commitment to ophthalmology and its global commercial infrastructure."

The NDA is supported by positive results from the comprehensive MIRA clinical program collectively involving over 600 subjects, including the MIRA-1 Phase 2b trial, MIRA-2 and MIRA-3 Phase 3 pivotal trials, and MIRA-4 Phase 3 pediatric trial. The MIRA-2 and MIRA-3 trials successfully met their primary and key secondary endpoints, demonstrating statistically significant superiority of Nyxol compared to placebo to rapidly return dilated eyes to their baseline pupil diameter as early as 60 and 90 minutes. The positive MIRA-4 pediatric trial results support a potential broader label for Nyxol in RM to include pediatric subjects aged 3 and older. In addition, Nyxol consistently showed a favorable safety and tolerability profile across all trials.

Ocuphire has received the $35 million upfront payment under the license agreement. Combined with its previous reported cash balance of $13.9 million at Sept 30, 2022, the Company believes that it has sufficient capital to fund operations into 2025, including advancing development of APX3330. If Nyxol is approved for RM in the US, Ocuphire is eligible to receive a $10 million milestone payment. For information on additional terms of the Nyxol license agreement, please refer to the Company's Current Report on Form 8-K filed on November 7, 2022.

About Nyxol

Nyxol is a proprietary, preservative-free, stable, investigational eye drop formulation of phentolamine mesylate 0.75% designed to uniquely modulate the pupil size by blocking the α1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. Nyxol is being developed for reversal of pharmacologically-induced mydriasis (RM), presbyopia, and night (or dim light) vision disturbances (NVD) under the 505(b)(2) pathway. Nyxol has been studied in a total of 12 clinical trials (3 Phase 1, 5 Phase 2, 4 Phase 3) in a total of approximately 1,100 patients (with over 650 Nyxol-treated) and has demonstrated promising clinical data for use in the multiple ophthalmic indications mentioned above. Ocuphire reported positive top-line data from the MIRA-1, MIRA-2, MIRA-3 and MIRA-4 trials in RM, Phase 3 LYNX-1 trial in NVD and Phase 2b VEGA-1 trial for Nyxol as single agent and as adjunctive therapy with 0.4% low dose pilocarpine in presbyopia.

About Ocuphire Pharma

Ocuphire is a publicly traded (Nasdaq: OCUP), clinical-stage, ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of refractive and retinal eye disorders.

The Company has a partnership with FamyGen Life Sciences and Viatris to develop and commercialize Nyxol® eye drops as a preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size, for three indications, including single-use for reversal of pharmacologically-induced mydriasis (RM), and once-daily for treatment of presbyopia and dim light or night vision disturbances (NVD), pending regulatory approval. Nyxol is currently in Phase 3 for presbyopia and NVD.

The Company's late-stage 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). APX3330 has been studied in 11 Phase 1 and 2 trials. The Company announced the completion of last patient last visit in late August with top-line results expected in early 2023 (NCT04692688).

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, statements concerning Ocuphire's potential receipt of payments, including regulatory and sales milestone payments, Ocuphire's potential receipt of royalty payments, Ocuphire's partnerships with Famy and Viatris, initiation of clinical trials, receipt of data from clinical trials, submission and receipt of regulatory approvals, including the potential approval of RM in the US, Ocuphire's business strategy and potential growth, timelines, and scope for global commercialization of Nyxol. 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) risks that the partnerships with Famy and Viatris may not facilitate the commercialization or market acceptance of Ocuphire's product candidates; (x) the success and timing of commercialization of any of Ocuphire's product candidates and (xi) 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.

Contacts

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