**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): **November 4, 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 and zip code)

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

(Registrant's 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:

☐ 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, par value $0.0001 per share | OCUP | The Nasdaq Stock Market LLC |

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 2.02 Results of Operations and Financial Condition.**

On November 4, 2022, Ocuphire Pharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated November 4, 2022 |
| 104 | Cover Page Interactive Data File (embedded with Inline XBRL document). |

**SIGNATURES**

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

**OCUPHIRE PHARMA, INC.**

Dated: November 4, 2022

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

**Exhibit 99.1**

# Ocuphire Pharma Announces Financial Results for Third Quarter 2022 and Provides Corporate Update

*NDA Submission for Nyxol for RM and Initiation of VEGA-2 on Track for Q4 2022*

*Topline Data from ZETA-1 Phase 2b Trial of Oral APX3330 Expected in Early 2023*

FARMINGTON HILLS, Mich., November 4, 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, announces financial results for the third quarter ended September 30, 2022 and provides a corporate update.

"During the third quarter, Ocuphire continued to execute elements of our strategic plan to bring innovative treatments to patients with highly prevalent refractive and diabetic retinal diseases," said Mina Sooch, MBA, founder and CEO of Ocuphire Pharma. "With enrollment and 24-week treatment completed in over 100 patients in our ZETA-1 Phase 2b trial of APX3330, we look forward to sharing topline results in early 2023, bringing us closer to delivering a potential oral option for diabetic retinopathy patients. We are on track for NDA submission for Nyxol for reversal of mydriasis in the fourth quarter 2022. We have strong momentum and are poised to deliver on multiple catalysts going forward that we believe will create significant value for our company and shareholders."

**Key Anticipated Future Milestones**

- **Reversal of Mydriasis (RM):** Plan to submit New Drug Application (NDA) with the FDA for Nyxol in RM indication in Q4 2022, with potential approval and commercial launch as first dilation reversal drop in 2023.
- **Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME):** Plan to report top-line results from the ZETA-1 Phase 2b trial of APX3330 in early 2023. APX3330 is a novel oral therapy with a dual mechanism of action in validated pathways, decreasing both abnormal angiogenesis and inflammation.
- **Presbyopia:** Plan to initiate VEGA-2 Phase 3 trial in Q4 2022 investigating Nyxol alone and Nyxol with 0.4% low-dose pilocarpine (LDP) as adjunctive therapy. In addition, VEGA-3 (2nd Phase 3) and LYRA-1 (1-year safety) trials are planned to begin in 2023.

**Third Quarter and Recent Business Highlights**

***Clinical and Regulatory Development***

- In September, the Company announced that the last of the 103 enrolled patients in the ZETA-1 Phase 2b trial of oral APX3330 for the treatment of diabetic retinopathy (DR) completed the final visit of the 24-week study.

- In September, the Company announced that U.S. Food and Drug Administration (FDA) has granted a small-business waiver of the Prescription Drug User Fee Act (PDUFA) fee of $3.1 million for the 505(b)(2) NDA for Nyxol.

***Presentations, Publications, and Conferences***

- Year to date, Ocuphire was represented at multiple key ophthalmological conferences with updates on Nyxol in RM, presbyopia and night vision disturbances, as well as masked safety data for APX3330 in DR. In total, more than 25 papers, posters, and panel talks were presented over 20 medical and industry conferences. Highlights in October and early November 2022:

    - Mitchell Jackson, MD presented a poster highlighting presbyopia data at the American Academy of Ophthalmology Annual Meeting in Chicago, IL.

    - Prominent optometry thought leaders and clinical trial investigators Justin Schweitzer, OD, Mitch Ibach, OD, Leslie O'Dell, OD, Shane Foster, OD, Doug , Devries, OD and Shane Kannarr, OD presented six posters on Nyxol and APX3330 at the American Academy of Optometry Annual Meeting in San Diego, CA.

    - The Company announced publication of an earlier Phase 2 clinical trial in patients with severe night vision disturbances in the BMC Ophthalmology peer-reviewed journal. The publication can be accessed here.

- In October, the Company held a Key Opinion Leader (KOL) webinar on oral APX3330. The event featured presentations by KOLs Peter Kaiser, MD, from the Cleveland Clinic, Caroline Baumal, MD, from Tufts Medical Center, and David Lally, MD, from New England Retina Consultants. KOL. The discussion highlighted the unmet need and current treatment landscape for DR/DME and included new data on study demographics and 24-week masked safety data from the ZETA-1 trial. A replay of the event can be found on the company's corporate website here.

***Corporate***

- On August 2, 2022, Ocuphire was granted extended intellectual property protection for Nyxol with the issuance of U.S. Patent No. 11,400,077 with claims directed to methods for mydriasis treatment using phentolamine, extended by 5 years into 2039.

- In September, the Company appointed seven new Key Opinion Leaders (KOLs) across retina, cornea/refractive, and medical optometry to its Medical Advisory Board (MAB): Anat Loewenstein, MD, PhD, Caroline Baumal, MD, Zaina Al-Mohtaseb, MD, Inder Paul Singh, MD, Leslie O'Dell, OD, Selina McGee, OD, Justin Schweitzer, OD.

**Third Quarter Ended September 30, 2022, Financial Highlights**

As of September 30, 2022, Ocuphire had cash and cash equivalents of approximately $13.9 million. Based on current projections, management believes the current cash on hand will be sufficient to fund operations into the fourth quarter of 2023. Net cash used in operating activities in the third quarter of 2022 was $4.5 million, with a cumulative total for the nine months ended September 30, 2022, of $14.5 million.

General and administrative expenses for the three and nine months ended September 30, 2022, were $1.7 million and $5.2 million, respectively, compared to $1.6 million and $6.7 million, respectively, for the three and nine months ended September 30, 2021. The increase from the comparable quarter in 2021 was largely attributed to an increase in legal costs on a net basis. The decrease from the comparable nine months in 2021 was largely attributed to a non-cash settlement with certain investors in the comparable prior year period, offset by a slight increase in general and administrative expenses attributed to higher payroll and other operating costs in the current year period when compared to the comparable prior year period.

Research and development expenses for the three and nine months ended September 30, 2022, were $2.8 million and $10.8 million, respectively, compared to $3.1 million and $10.4 million, respectively, for the three and nine months ended September 30, 2021. The decrease from the comparable quarter in 2021 was primarily attributable to the completion of clinical trials and the timing of manufacturing activities for Nyxol and APX3330. The increase from the comparable nine months in 2021 was primarily attributable to the timing of clinical trials and manufacturing activities for Nyxol and APX3330 as well as regulatory, preclinical and other development activities.

The total loss from operations for the three and nine months ended September 30, 2022, was $4.5 million and $16.0 million, respectively, compared to $4.2 million and $16.6 million, respectively, for the three and nine months ended September 30, 2021.

Net loss for the three and nine months ended September 30, 2022, was $4.5 million and $16.1 million, respectively, compared to $4.2 million and $50.4 million, respectively, for the three and nine months ended September 30, 2021. Net loss per share for the three and nine months ended September 30, 2022, was ($0.22) and ($0.82) per share, respectively, compared to ($0.25) and ($3.64) per share, respectively, for the comparable periods in 2021.

For further details on Ocuphire's financial results, refer to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, to be filed with the Securities and Exchange Commission.

**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'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 three indications, including reversal of pharmacologically induced mydriasis (RM), presbyopia and dim light or night vision disturbances (NVD). Nyxol has been studied in 12 completed clinical trials, including recently reported positive data from the following trials:

- MIRA-2 (NCT04620213), MIRA-3 (NCT05134974), and MIRA-4 (NCT05223478 pediatric safety trial) registration trials for the treatment of RM
- VEGA-1 (NCT04675151) Phase 2 trial of Nyxol for treatment of presbyopia, which evaluated both Nyxol as a single agent and Nyxol with low dose pilocarpine ("LDP") 0.4% as adjunctive therapy
- LYNX-1 (NCT04638660) Phase 3 trial of Nyxol for night vision disturbances (NVD)

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). APX3330 has been studied in 11 Phase 1 and 2 trials. The Company announced the completion of last patient last visit in late August in ZETA-1 (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 clinical and regulatory milestones for Ocuphire's indications, including Ocuphire's potential NDA submission, initiation of certain trials, and receipt of topline data, Ocuphire's business strategy and potential growth, 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.

**Contacts**


| Corporate | Investor Relations | |
|---|---|---|
| Mina Sooch, MBA<br>CEO & Founder<br>ir@ocuphire.com | Corey Davis, Ph.D.<br>LifeSci Advisors<br>cdavis@lifesciadvisors.com | Bret Shapiro<br>CoreIR<br>brets@coreir.com |

**Ocuphire Pharma, Inc.**
**Condensed Balance Sheets**
**(in thousands, except share amounts and par value)**

| | As of | |
|---|---|---|
| | **September 30, 2022** | **December 31, 2021** |
| | **(unaudited)** | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,855 | $ 24,534 |
| Prepaids and other current assets | 605 | 1,314 |
| Short-term investments | 101 | 219 |
| Total current assets | 14,561 | 26,067 |
| Property and equipment, net | 7 | 10 |
| Total assets | $ 14,568 | $ 26,077 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,468 | $ 1,584 |
| Accrued expenses | 1,223 | 1,733 |
| Short-term loan | — | 538 |
| Total current liabilities | 2,691 | 3,855 |
| Warrant liabilities | — | — |
| Total liabilities | 2,691 | 3,855 |
| | | |
| Commitments and contingencies | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock, par value $0.0001; 10,000,000 shares authorized as of September 30, 2022, and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021. | — | — |
| Common stock, par value $0.0001; 75,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 20,801,506 and 18,845,828 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively. | 2 | 2 |
| Additional paid-in-capital | 117,296 | 111,588 |
| Accumulated deficit | (105,421) | (89,368) |
| Total stockholders' equity | 11,877 | 22,222 |
| Total liabilities and stockholders' equity | $ 14,568 | $ 26,077 |

**Ocuphire Pharma, Inc.**
**Condensed Consolidated Statements of Comprehensive Loss**
**(in thousands, except share and per share amounts)**
**(Unaudited)**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Collaborations revenue | $ — | $ 489 | $ — | $ 589 |
| Operating expenses: | | | | |
| General and administrative | 1,703 | 1,595 | 5,215 | 6,707 |
| Research and development | 2,835 | 3,126 | 10,769 | 10,437 |
| Total operating expenses | 4,538 | 4,721 | 15,984 | 17,144 |
| Loss from operations | (4,538) | (4,232) | (15,984) | (16,555) |
| Interest expense | — | — | (9) | — |
| Fair value change of warrant liabilities | — | — | — | (33,829) |
| Other income (expense), net | 7 | 2 | (60) | 4 |
| Loss before income taxes | (4,531) | (4,230) | (16,053) | (50,380) |
| Benefit (provision) for income taxes | — | — | — | — |
| Net loss | (4,531) | (4,230) | (16,053) | (50,380) |
| Other comprehensive loss, net of tax | — | — | — | — |
| Comprehensive loss | $ (4,531) | $ (4,230) | $ (16,053) | $ (50,380) |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.22) | $ (0.25) | $ (0.82) | $ (3.64) |
| Number of shares used in per share calculations: | | | | |
| Basic and diluted | 20,498,229 | 16,925,006 | 19,635,651 | 13,841,067 |