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 30, 2023**

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 March 30, 2023, Ocuphire Pharma, Inc. (the "Company") issued a press release announcing its financial results for the year and quarter ended December 31, 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 March 30, 2023
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: March 30, 2023

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

Exhibit 99.1

Ocuphire Pharma Announces Financial Results for Fourth Quarter and Year Ended 2022 and Provides Corporate Update

Financial Profile Improved Markedly with Global License Agreement to Develop and Commercialize Nyxol for All Three Indications with Cash Runway into 2025

PDUFA Date of September 28, 2023 Set for Nyxol® in its First Indication, Reversal of Pharmacologically-induced Mydriasis; $10 Million Milestone Linked to Approval

Oral APX3330 Achieved Statistical Significance on a Potential Registration Endpoint for Diabetic Retinopathy in ZETA-1 Trial; End-of-Phase 2 FDA Meeting Planned

FARMINGTON HILLS, Mich., March 30, 2023 – 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 financial results for the fourth quarter and year ended December 31, 2022 and provided a corporate update.

“2022 proved to be a year of significant clinical, regulatory, patent, and strategic partner milestones, positioning the company for further success in 2023,” said Mina Sooch, MBA, founder and CEO of Ocuphire Pharma. “Our first NDA for Nyxol in the reversal of pharmacologically-induced mydriasis has a PDUFA action date the FDA this September, and we look forward to working with the FDA through the regulatory review process. For APX3330, our oral candidate for diabetic eye disease, the ZETA-1 Phase 2 trial achieved statistical significance on a potential registration endpoint of slowing progression of diabetic retinopathy, and we are preparing for an End-of-Phase 2 meeting. Across the Nyxol and APX3330 programs, we are poised for potential late-stage clinical, regulatory, and product approval catalysts in 2023.”

Cam Gallagher, Ocuphire’s Chairman of the Board added, “Our collaboration with Viatris is transformative for the company, and we are excited with Viatris having selected the Nyxol portfolio of indications as one of the key elements of its plan to create a global eye care leader. The partnership provides an externally financed pathway to completing development and regulatory activities for Nyxol and to executing successful US and global commercial launches, if approved. The financial elements of the agreement have greatly strengthened the balance sheet and provides capital to advance the APX3330 program to a pivotal stage.

Key Anticipated Future Milestones

Partner or OCUP Name	Study	Milestone	Anticipated Indication	1H 2023	2H 2023
APX3330	ZETA-1	End of Phase 2 FDA meeting	Diabetic Retinopathy		•
MR-140 (Nyxol)	MIRA program	PDUFA date Sept 28, 2023	Reversal of Pharmacologically-induced Mydriasis		•
MR-141 (Nyxol and Nyxol+LDP)	VEGA-3	Initiate 2nd Phase 3 trial	Presbyopia	•	
	VEGA-2	Report 1st Phase 3 topline data	Presbyopia		•
MR-142 (Nyxol)	LYNX-2	Initiate 2nd Phase 3 trial	Night Vision or Dim Light Disturbances (DLD)	•	
MR-141 and MR-142 (Nyxol)	LYRA-1	Initiate long-term safety trial	Presbyopia and DLD	•	

Recent Business Highlights

Advances in Clinical and Regulatory Development

- In February 2023, the Company announced that U.S. Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for Nyxol in RM and set a PDUFA date of September 28, 2023. The NDA was submitted in November 2022 and was supported by positive results from the comprehensive MIRA clinical programs (MIRA-1, MIRA-2, MIRA-3 and MIRA-4) collectively involving over 600 subjects, including pediatric subjects over 3 years old.

- In January 2023, the Company announced topline results from the ZETA-1 Phase 2 trial of oral APX3330 for the treatment of diabetic retinopathy (DR). Oral APX3330 achieved statistical significance on a key pre-specified secondary endpoint of binocular ≥ 3-step worsening of DRSS and demonstrated favorable safety and tolerability after 24 weeks of treatment. This binocular secondary endpoint is a potential Phase 3 registration endpoint which the Company plans a meeting with the FDA to formally agree on this endpoint and Phase 3 development in an End-of-Phase 2 meeting in 2H 2023. The safety and tolerability of APX3330 were favorable in diabetic patients and consistent with prior trials in non-ophthalmic indications. Prevention of progression is a clinically meaningful outcome that may change the treatment paradigm for a large number of diabetic retinopathy (DR) patients.

- In January 2023, the Company announced the initiation of the VEGA-2 Phase 3 pivotal trial, with the first patient enrolled in late December. VEGA-2 is evaluating treatment efficacy and safety for two labels for presbyopia: Nyxol alone and Nyxol with adjunctive Low Dose Pilocarpine (LDP) therapy. The Company plans to initiate a second Phase 3 pivotal trial in presbyopia (VEGA-3), and a one-year safety study (LYRA-1) in 2023.

Presentations, Publications, and Conferences

- From January 2022 through March 2023, more than 20 papers, posters, and panel talks were presented at over 30 medical and industry conferences with updates on Nyxol in RM by Justin Schweitzer, OD, Leslie O'Dell, OD and Shane Foster, OD, presbyopia by Mitch Jackson, MD and Mitch Ibach, OD, and night vision disturbances by Shane Kannarr, OD and on APX3330 in DR by Douglas Devries, OD, Peter Kaiser, MD and Rishi Singh, MD.

- In November 2022, 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 2022, the Company held a key opinion leader (KOL) webinar on oral APX3330 featuring 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. A replay of the event, including slides, can be found on the corporate website here.

Intellectual Property

- For the Nyxol Program:
    - The United States Patent & Trademark Office (USPTO) issued U.S. Patent No. 11,400,077 in August 2022 with claims directed to methods for treating mydriasis using phentolamine mesylate, which has a term extending into year 2039.
    - The USPTO issued U.S. Patent No. 11,566,005 in January 2023 with claims directed polymorphic forms of phentolamine mesylate and methods using and preparing the same, which has a term extending into year 2042.

- For the APX3330 Program:
    - The USPTO issued U.S. Patent No. 11,351,130 in June 2022 with claims directed to methods of treating inflammation and chronic pain using APX3330 in combination with certain additional therapeutic agents, which has a term extending into year 2038, not including any patent term extension.

- The European Patent Office issued European Patent No. 3725309 in November 2022 with claims directed to APX3330 for use in inhibiting advanced macular degeneration, which has a term extending to year 2028, not including any supplementary protection certificate.

Corporate

- In November, the Company entered into an exclusive license agreement with FamyGen Life Sciences, Inc. (Famy), which was subsequently acquired by Viatris Inc. (Nasdaq: VTRS), for the development and commercialization of Nyxol across three indications in US, Europe, Japan, India, China and other global markets. Viatris, a leading global healthcare company will be responsible for the commercialization of Nyxol following each regulatory approval. Under the terms of the agreement, Ocuphire received an upfront payment of $35 million. Ocuphire has the potential to receive a $10 million milestone payment upon FDA approval for the RM indication later in 2023 and thereafter to receive additional regulatory milestone payments for presbyopia and night vision disturbances indications. Upon commercialization, Ocuphire will receive tiered double-digit royalties on worldwide net sales through 2040 and is eligible to receive sales milestone payments upon achievement of certain annual sales thresholds.

Fourth Quarter Ended December 31, 2022 Financial Highlights

As of December 31, 2022, Ocuphire had cash and cash equivalents of approximately $42.6 million. The Company has no debt. Based on current projections, management believes the present cash on hand will be sufficient to fund operations into 2025.

License and collaborations revenue was $39.9 million for the quarter and year ended December 31, 2022, compared to zero and $0.6 million for the quarter and year ended December 31, 2021, respectively. Revenue during 2022 was derived from the Nyxol License Agreement signed with Famy in the fourth quarter of the year.

General and administrative expenses for the quarter and year ended December 31, 2022 were $2.1 million and $7.3 million, respectively, compared to $1.4 million and $8.1 million for the quarter and year ended December 31, 2021, respectively. The decrease in the year over year period was primarily attributable to a non-cash settlement cost in 2021, decreases in stock-based compensation and other operating expenses. Partially offsetting the expense decreases from the prior year were increases in administrative employee headcount costs, legal fees and professional service costs. General and administrative expenses included $1.1 million in stock-based compensation expense in each of the years ended December 31, 2022, and 2021.

Research and development expenses for the quarter and year ended December 31, 2022 were $3.6 million and $14.4 million, respectively, compared to $4.7 million and $15.2 million for the quarter and year ended December 31, 2021, respectively. The decrease in the year over year period was primarily attributable to decreases in contract research organization expenses along with an associated decrease in manufacturing activities, offset in part by cost increases attributable to staff headcount and consulting services, as well as increases attributable to regulatory and other research and development efforts. Research and development expenses also included $0.7 million and $0.8 million in stock-based compensation expense during the years ended December 31, 2022 and 2021, respectively.

Net income for year ended December 31, 2022 was $17.9 million compared to a net loss of $56.7 million for the year ended December 31, 2021. The $56.7 million net loss in 2021 included a non-cash expense of $33.8 million related to the fair value change in warrant liabilities. Net income for the fourth quarter ended December 31, 2022 was $33.9 million compared with a net loss of $6.3 million in the comparable period of 2021.

Basic net income per share for the quarter and year ended December 31, 2022 was $1.63 and $0.90 per share, respectively, compared to a basic and diluted net loss per share of ($0.35) and ($3.82) per share, respectively, for the comparable periods in 2021. Diluted net income per share for the quarter and year ended December 31, 2022 was $1.58 and $0.87 per share, respectively.

For further details on Ocuphire's financial results, refer to the Company's Annual Report on Form 10-K for the year ended December 31, 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.

Ocuphire has a partnership with Viatris, Inc. 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 by uniquely blocking the alpha-1 receptors found only on the iris dilator muscle without affecting the ciliary muscle. Nyxol has been studied in a total of 12 clinical trials (3 Phase 1, 5 Phase 2, 4 Phase 3) across three indications, including single-use for reversal of pharmacologically-induced mydriasis (RM), and once-daily for treatment of presbyopia and dim light (night) vision disturbances (DLD), pending regulatory approvals. Nyxol's NDA under the 505(b)(2) pathway for the first indication, RM, has been accepted with a PDUFA date assigned of September 28, 2023. Nyxol is currently in Phase 3 for presbyopia and DLD.

Ocuphire's other late-stage product candidate, APX3330, is a first-in-class, small molecule oral drug that blocks downstream pathways regulated by transcription factor Ref-1 – including those involving angiogenesis (VEGF) and inflammation (NFkB). These pathways are implicated across several ocular diseases, including diabetic retinopathy (DR), diabetic macular edema (DME), and age-related macular degeneration (AMD). Ocuphire recently announced topline data from the ZETA-1 Phase 2 trial in which APX3330 achieved statistical significance on a key pre-specified secondary endpoint of preventing clinically meaningful progression of DR after 24 weeks of daily treatment. APX3330 has also shown a favorable safety and tolerability profile in diabetic subjects (ZETA-1 trial) and in 11 previous clinical trials conducted in healthy, liver disease, and cancer subjects. An End-of-Phase 2 meeting with the FDA is planned for APX3330.

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 the potential receipt of regulatory approval for Nyxol for the treatment of RM, the potential to submit supplementary NDAs for presbyopia and DLD, the potential market opportunity for Nyxol, the success and timing of planned future clinical trials timing and occurrence of an End-of-Phase 2 meeting for APX3330 with the FDA, the potential of a Phase 3 registration path for APX3330, the potential market opportunity for APX3330, the success and timing of planned regulatory filings, anticipated cash runway, and Ocuphire's business strategy. 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 macroeconomic conditions on business operations, (ix) risks that the Nyxol partnership 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

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

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

	As of December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 42,634	$ 24,534
Accounts receivable	1,298	—
Contract asset	3,552	—
Prepaids and other current assets	1,453	1,314
Short-term investments	49	219
Total current assets	48,986	26,067
Property and equipment, net	6	10
Total assets	$ 48,992	$ 26,077
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,069	$ 1,584
Accrued expenses	1,684	1,733
Short-term loan	—	538
Total current liabilities	2,753	3,855
Warrant liabilities	—	—
Total liabilities	2,753	3,855
Commitments and contingencies		
Stockholders' equity		
Preferred stock, par value $0.0001; 10,000,000 shares authorized as of December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021.	—	—
Common stock, par value $0.0001; 75,000,000 shares authorized as of December 31, 2022 and 2021; 20,861,315 and 18,845,828 shares issued and outstanding at December 31, 2022 and 2021, respectively.	2	2
Additional paid-in capital	117,717	111,588
Accumulated deficit	(71,480)	(89,368)
Total stockholders' equity	46,239	22,222
Total liabilities and stockholders' equity	$ 48,992	$ 26,077

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

	For the Year Ended December 31,	
	2022	**2021**
License and collaborations revenue	$ 39,850	$ 589
Operating expenses:		
General and administrative	7,269	8,121
Research and development	14,355	15,173
Total operating expenses	21,624	23,294
Income (loss) from operations	18,226	(22,705)
Interest expense	(9)	(2)
Fair value change in warrant liabilities	—	(33,829)
Other expense, net	(14)	(157)
Income (loss) before income taxes	18,203	(56,693)
Provision for income taxes	(315)	—
Net income (loss)	17,888	(56,693)
Other comprehensive income (loss), net of tax	—	—
Comprehensive income (loss)	$ 17,888	$ (56,693)
Net income (loss) per share:		
Basic	$ 0.90	$ (3.82)
Diluted	$ 0.87	$ (3.82)
Number of shares used in per share calculations:		
Basic	19,931,080	14,852,745
Diluted	20,597,212	14,852,745

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

	For the Quarter Ended December 31,	
	2022	**2021**
License and collaborations revenue	$ 39,850	$ —
Operating expenses:		
General and administrative	2,054	1,414
Research and development	3,586	4,736
Total operating expenses	5,640	6,150
Income (loss) from operations	34,210	(6,150)
Interest expense	—	(2)
Fair value change in warrant liabilities	—	—
Other expense, net	46	(161)
Income (loss) before income taxes	34,256	(6,313)
Provision for income taxes	(315)	—
Net income (loss)	33,941	(6,313)
Other comprehensive income (loss), net of tax	—	—
Comprehensive income (loss)	$ 33,941	$ (6,313)
Net income (loss) per share:		
Basic	$ 1.63	$ (0.35)
Diluted	$ 1.58	$ (0.35)
Number of shares used in per share calculations:		
Basic	20,807,734	17,854,790
Diluted	21,476,348	17,854,790