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 8, 2024

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** (Address of principal executive offices)	**48335** (Zip Code)

Registrant's telephone number, including area code: **(248) 957-9024**

(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, $0.0001 par value 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 8, 2024, Ocuphire Pharma, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2023. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 of this Current Report on Form 8-K, and Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Dated: March 8, 2024

OCUPHIRE PHARMA, INC.

By: /s/ Dr. George Magrath
Name: Dr. George Magrath
Title: Chief Executive Officer

Exhibit 99.1

Ocuphire Pharma Announces Financial Results for Fourth Quarter and Full Year 2023 and Provides Corporate Update

FARMINGTON HILLS, Mich., March 8, 2024 (GLOBE NEWSWIRE) – Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders, today announced financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

"Ocuphire had a successful 2023, with notable achievements on the regulatory and development fronts, paving the way for further progress in the year ahead," said George Magrath, M.D., M.B.A., M.S., CEO of Ocuphire. "Our strategic focus is on the advancement of our retina pipeline, and we are preparing our late-stage clinical program to progress APX3330 in diabetic retinopathy ("DR"). We believe APX3330 may represent a promising oral treatment option for delaying disease progression in patients with non-proliferative diabetic retinopathy who otherwise are monitored and untreated until they progress to sight-threatening disease."

Clinical and Regulatory Updates

APX3330

- In January 2023, Ocuphire reported top-line efficacy and safety results from the ZETA-1 Phase 2 trial conducted in 103 subjectswith DR, including moderately severe and severe non-proliferative DR ("NPDR") and mild proliferative DR ("PDR"), as well as patients with diabetic macular edema without loss of central vision. Trends toward efficacy were seen on the ≥3-step worsening on a binocular diabetic retinopathy severity scale ("DRSS") Person Scale. APX3330 also demonstrated favorable safety and tolerability in diabetic patients.

- In October 2023, Ocuphire held an End-of-Phase 2 meeting with the FDA and aligned on the registrational primary endpoint of 3-step or more worsening on binocular DRSS Person scale.

- In February 2024, Ocuphire submitted a Special Protocol Assessment ("SPA") to seek agreement on the clinical trial protocol and statistical analysis plan for Phase 3. Specifics on the study design and the anticipated timing will be shared if and when an agreement is reached with the FDA.

Phentolamine ophthalmic solution 0.75% (“PS”)

- In September 2023, Ocuphire and Viatris, Inc. (“Viatris”) announced FDA approval of PS under the brand name RYZUMVI™ for the treatment of pharmacologically-induced mydriasis. In 2023, the Company received a cash payment in the amount of $10 million from Viatris upon achieving this regulatory approval milestone in connection with its license agreement with Viatris. RYZUMVI is expected to launch in the first half of 2024.

- The Company received an agreement from the FDA under a SPA for the clinical trial protocol and planned statistical analysis of the LYNX-2 Phase 3 trial to evaluate PS for the proposed indication for the treatment of decreased visual acuity under dim (mesopic) light conditions after keratorefractive surgery. Viatris is expected to continue Phase 3 development of this indication in the first half of 2024.

- The VEGA-2 Phase 3 study achieved a primary endpoint in presbyopia. Viatris is expected to continue Phase 3 development in the first half 2024.

- Development of PS in treatment of presbyopia and in decreased visual acuity under dim (mesopic) light conditions after keratorefractive surgery is expected to be funded by Viatris, under terms of the license agreement with Viatris.

Corporate Updates

- In August 2023, Ocuphire entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC (“LPC”), pursuant to which Ocuphire has the sole right, but not the obligation, to direct LPC to purchase up to $50 million of shares of our common stock.

- In November 2023, Ocuphire appointed George Magrath, M.D., M.B.A., M.S., as Chief Executive Officer and as a member of the Board of Directors. Dr. Magrath succeeded Rick Rodgers, M.B.A., Interim Chief Executive Officer and President. Mr. Rodgers remains a member of the Board of Directors.

- In November 2023, Ocuphire appointed Joseph (Joe) K. Schachle, M.B.A., as Chief Operating Officer.

- In February 2024, Ocuphire appointed Nirav Jhaveri, C.F.A, M.B.A. as Chief Financial Officer and Ashwath (Ash) Jayagopal, Ph.D., M.B.A. as Chief Scientific and Development Officer.

Financial Highlights for the Fourth Quarter and Full Year Ended December 31, 2023

As of December 31, 2023, Ocuphire had cash and cash equivalents of approximately $50.5 million. Based on current projections, management believes the present cash on hand will be sufficient to fund operations into mid-2025.

License and collaboration revenue was $1.7 million and $19.0 million for the fourth quarter and year ended December 31, 2023, respectively, compared to $39.9 million for both the fourth quarter and year ended December 31, 2022. Revenue during 2023 was derived in part from a milestone payment of $10.0 million received from Viatris and attributed to the FDA's approval of RYZUMVI for the treatment of pharmacologically induced mydriasis. The balance of the revenue recognized during calendar year 2023 related to the output of research and development services in connection with the Viatris License Agreement. Revenue during calendar year 2022 was derived from the Viatris License Agreement signed in the fourth quarter, and to a lesser extent, from the reimbursement by Viatris of research and development services

General and administrative expenses were $3.3 million and $12.0 million for the fourth quarter and year ended December 31, 2023, respectively, compared to $2.1 million and $7.3 million for the fourth quarter and year ended December 31, 2022. The increase year-over-year was attributed to payroll related costs, stock-based compensation, other personnel related costs, professional services fees, legal support, and business development activities and other costs. General and administrative expenses included $2.4 million and $1.1 million in stock-based compensation expense during the years ended December 31, 2023 and 2022, respectively.

Research and development expenses were $3.8 million and $17.7 million for the fourth quarter and year ended December 31, 2023, respectively, compared to $3.6 million and $14.4 million for the fourth quarter and year ended December 31, 2022. The increase was primarily attributable to increased clinical costs for PS, increased manufacturing and toxicology activities for APX3330 and PS, higher payroll costs including stock-based compensation, and other operating expenses. These were offset by a decrease in regulatory activities. Pursuant to the Viatris License Agreement, Ocuphire's budgeted research and development expenses related to the development of PS are fully reimbursed by Viatris. Research and development expenses included $1.1 million and $0.7 million in stock-based compensation expense during the years ended December 31, 2023, and 2022, respectively.

Net loss was $4.8 million (or ($0.21) per basic and diluted share) and $10.0 million (or ($0.46) per basic and diluted share), for the fourth quarter and year ended December 31, 2023, respectively. This compared to net income of $33.9 million (or $1.63 per basic share and $1.58 per diluted share) and $17.9 million (or $0.90 per basic share and $0.87 per diluted share), for the fourth quarter and the year ended December 31, 2022, respectively.

For further details on Ocuphire's financial results, refer to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, to be filed with the Securities and Exchange Commission (the "SEC").

About Ocuphire Pharma

Ocuphire is a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of retinal and refractive eye disorders.

Ocuphire's lead retinal product candidate, APX3330, is a small-molecule inhibitor of Ref-1 (reduction oxidation effector factor-1 protein). Ref-1 is a regulator of the transcription factors HIF-1α and NF-κB. Inhibiting REF-1 reduces levels of vascular endothelial growth factor ("VEGF") and inflammatory cytokines which are known to play key roles in ocular angiogenesis and inflammation. APX3330 is an oral tablet to be administered twice per day for the treatment of DR. A Phase 2 study in subjects with DR and an End-of-Phase 2 meeting have recently been completed, and a SPA is planned to be submitted.

DR affects approximately 10 million people with diabetes and is projected to impact over 14 million Americans by 2050. DR is classified as NPDR, the early stage of the disease in which symptoms may be mild or non-existent or PDR, which is the more advanced stage of diabetic eye disease that can be highly symptomatic with loss of vision. Approximately 8 million DR patients have NPDR that will progress to PDR, if left untreated. Despite the risk for visual loss associated with this disease, over 90% of NPDR patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is partially attributed to the currently approved therapies for this disease. APX3330 as an oral tablet has the potential to be an early, non-invasive treatment for the 8 million NPDR patients in the U.S. Treatment with APX3330 is expected to delay or prevent progression of NPDR, thereby reducing the need for expensive intravitreal injections with anti-VEGF therapies and reducing the likelihood of vision loss due to DR.

Ocuphire has also in-licensed APX2009 and APX2014, which are second-generation analogs of APX3330. The unique mechanism of action of these Ref-1 inhibitors, which reduce both angiogenesis and inflammation, could potentially be beneficial in treating other retinal diseases such as age-related macular degeneration and geographic atrophy. Ocuphire is currently evaluating local delivery routes in addition to the systemic (oral) route as part of its pipeline expansion in retinal therapies. Ocuphire also has a partnership with Viatris, Inc. to develop and commercialize PS (initially known as Nyxol). PS is a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size by uniquely blocking the alpha-1 receptors found on the iris dilator muscle without affecting the ciliary muscle. PS was approved by the FDA for the treatment for pharmacologically-induced mydriasis under the brand name RYZUMVI™ in September 2023. PS is also in Phase 3 clinical development for the treatment of presbyopia and for the treatment of decreased visual acuity under dim (mesopic or low) light conditions after keratorefractive surgery.

For more information, visit www.ocuphire.com.

Forward Looking Statements

This press release 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 the End-of-Phase 2 meeting with the FDA to align on late-stage registration endpoints and study parameters, the launching of RYZUMVI, the continued development of PS and LDP, the sufficiency of cash on hand to meet future funding needs, and the potential of APX3330 as an oral treatment for patients with non-proliferative diabetic retinopathy.

These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in our Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

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:

- The success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts;
- Regulatory requirements or developments;
- Changes to or unanticipated events in connection with clinical trial designs and regulatory pathways;
- Delays or difficulties in the enrollment of patients in clinical trials;
- Substantial competition and rapid technological change;
- Our development of sales and marketing infrastructure;
- Future revenue losses and profitability;
- Our relatively short operating history;
- Changes in capital resource requirements;
- Risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs;
- Domestic and worldwide legislative, regulatory, political and economic developments;

- Employee misconduct;
- Changes in market opportunities and acceptance;
- Reliance on third-parties;
- Future, potential product liability and securities litigation;
- System failures, unplanned events, or cyber incidents;
- The substantial number of shares subject to potential issuance associated with our Equity Line of Credit arrangement with LPC;
- Risks that our partnership with Viatris, or our other licensing arrangements, may not facilitate the commercialization or market acceptance of Ocuphire's product candidates;
- Future fluctuations in the market price of our common stock;
- The success and timing of commercialization of any of Ocuphire's product candidates; and
- Obtaining and maintaining 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. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the SEC that advise interested parties of the risks and factors that may affect our business. 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
George Magrath, M.D., M.B.A., M.S. CEO ir@ocuphire.com	Corey Davis, Ph.D. LifeSci Advisors cdavis@lifesciadvisors.com

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

	As of December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 50,501	$ 42,634
Accounts receivable	926	1,298
Contract assets and unbilled receivables	1,407	3,552
Prepaids and other current assets	1,099	1,453
Short-term investments	15	49
Total current assets	53,948	48,986
Property and equipment, net	—	6
Total assets	$ 53,948	$ 48,992
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,153	$ 1,069
Accrued expenses	1,815	1,684
Derivative liability	74	—
Total current liabilities	4,042	2,753
Total liabilities	4,042	2,753
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.0001; 10,000,000 shares authorized as of December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022.	—	—
Common stock, par value $0.0001; 75,000,000 shares authorized as of December 31, 2023 and 2022; 23,977,491 and 20,861,315 shares issued and outstanding at December 31, 2023 and 2022, respectively.	2	2
Additional paid-in capital	131,370	117,717
Accumulated deficit	(81,466)	(71,480)
Total stockholders' equity	49,906	46,239
Total liabilities and stockholders' equity	$ 53,948	$ 48,992

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

	For the Year Ended December 31,		For the Three Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
License and collaborations revenue	$ 19,049	$ 39,850	$ 1,691	$ 39,850
Operating expenses:				
General and administrative	11,959	7,269	3,279	2,054
Research and development	17,653	14,355	3,841	3,586
Total operating expenses	29,612	21,624	7,120	5,640
(Loss) income from operations	(10,563)	18,226	(5,429)	34,210
Financing costs	(1,328)	—	—	—
Interest expense	—	(9)	—	—
Fair value change in derivative liabilities	80	—	19	—
Other income (expense), net	1,837	(14)	613	46
(Loss) income before income taxes	(9,974)	18,203	(4,797)	34,256
Provision for income taxes	(12)	(315)	2	(315)
Net (loss) income	(9,986)	17,888	(4,795)	33,941
Other comprehensive (loss) income, net of tax	—	—	—	—
Comprehensive (loss) income	$ (9,986)	$ 17,888	$ (4,795)	$ 33,941
Net (loss) income per share:				
Basic	$ (0.46)	$ 0.90	$ (0.21)	$ 1.63
Diluted	$ (0.46)	$ 0.87	$ (0.21)	$ 1.58
Number of shares used in per share calculations:				
Basic	21,589,821	19,931,080	22,992,239	20,807,734
Diluted	21,589,821	20,597,212	22,992,239	21,476,348