

**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 10, 2021

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).

Item 2.02**Results of Operations and Financial Condition.**

On March 10, 2021, Ocuphire Pharma, Inc. (the “*Registrant*”) issued a press release announcing its financial results for the year ended December 31, 2020. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current 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 Registrant’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 Number	Exhibit Description
99.1	Press Release, dated March 10, 2021.

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.

OCUPHIRE PHARMA, INC.

By: /s/ Mina Sooch

Mina Sooch
Chief Executive Officer

Date: March 11, 2021

Ocuphire Announces Financial Results for the Full Year 2020 and Provides Corporate Update

March 10, 2021

FARMINGTON HILLS, Mich., March 10, 2021 (GLOBE NEWSWIRE) -- Ocuphire Pharma, Inc. (Nasdaq: OCUP), a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of several eye disorders, today announced financial results for the full year 2020 and provided a corporate update.

“2020 was a transformative year for Ocuphire, with significant achievements on clinical, corporate and financial fronts. We became a Nasdaq-listed company through our reverse merger with Rexahn Pharmaceuticals and raised just over \$21 million concurrent with the merger,” said Mina Sooch, MBA, President and CEO of Ocuphire Pharma. “Despite the challenges of the COVID-19 pandemic, we consistently hit our planned milestones throughout the year, including initiating multiple Phase 3 and Phase 2 clinical trials and completing enrollment on one Phase 3 trial, and publishing results of two prior Phase 2 trials. We look forward to building on this progress in 2021 as we move forward with our promising Nyxol[®] and APX3330 programs.”

Key Anticipated Future Milestones

- Phase 3 MIRA-2 trial investigating Nyxol for Reversal of Mydriasis with top line data expected in March 2021
- Phase 2 VEGA-1 trial investigating a kit combination of Nyxol and low-dose pilocarpine for treatment of Presbyopia with top line data expected end of Q2 2021
- Phase 3 LYNX-1 trial investigating Nyxol for Night Vision Disturbances with top line data expected end of Q3 2021
- Phase 2 ZETA-1 trial investigating APX3330 for Diabetic Retinopathy and Diabetic Macular Edema: enrollment initiation expected in Q1 2021 with top line data expected early 2022

Recent Business Highlights

Clinical

- Phase 3 MIRA-2 trial investigating Nyxol for Reversal of Mydriasis enrollment initiated and completed
 - Phase 3 LYNX-1 trial investigating Nyxol in Night Vision Disturbances initiated
 - Phase 2 trial VEGA-1 to evaluate a combination kit of Nyxol and low-dose pilocarpine in presbyopia initiated
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Publications / Grants

- Results from ORION-1 Phase 2b trial evaluating the safety and efficacy of Nyxol in glaucoma and presbyopia published in *Clinical Ophthalmology*
- Results from MIRA-1 Phase 2b trial evaluating the safety and efficacy of Nyxol in the reversal of mydriasis (dilation of pupil for eye exams) published in *Optometry and Visual Science*
- Data on the benefits of Ref-1 inhibition via APX3330 demonstrating its potential to treat multiple inflammatory and angiogenic disease processes published in *Drug Discovery Today* and *Inflammatory Bowel Disease*

Corporate

- Completed reverse merger with Rexahn Pharmaceuticals and are a publicly traded company listed on the Nasdaq Capital Market as OCUP as of November 6, 2020
- Raised \$21.15 million in a private placement led by institutional healthcare and accredited investors
- Participating in multiple Presbyopia events in early 2021 - *Discussion on New Advances for Presbyopia, OIS Presbyopia Innovation Forum, and Eyeing Key Events and Programs in the Ophthalmology Space in 2021*

2020 Financial Highlights

At December 31, 2020, the company had cash and cash equivalents of approximately \$16.4 million.

General and administrative expenses for the year ended December 31, 2020 were \$2.8 million compared to \$1.8 million for the year ended December 31, 2019. The \$1.0 increase was primarily attributable to an increase in stock-based compensation, professional services, insurance, and legal costs associated with the reverse merger in the current period.

Research and development expenses for the year ended December 31, 2020 were \$6.6 million compared to \$2.4 million for the year ended December 31, 2019. The \$4.3 million increase was primarily attributable to clinical trials and manufacturing activities to support clinical advancement of Nyxol as well as regulatory and business development efforts.

Net loss attributable to common stockholders for the year ended December 31, 2020 was \$24.6 million compared to \$6.2 million for the year ended December 31, 2019.

For further details on Ocuphire's financial results, refer to our annual report on form 10K for fiscal year 2020, to be filed with the SEC.

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 front and back of the eye indications. The company's lead product candidate, Nyxol[®] Eye Drops, 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 dim light or night vision disturbances (NVD), reversal of pharmacologically-induced mydriasis (RM), and presbyopia, and has been studied in 7 Phase 1 and 2 trials. 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. Nyxol is entering Phase 3 clinical development for NVD and RM, and Phase 2 for presbyopia. APX3330 is entering Phase 2 clinical development for DR/DME. 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. Please visit www.clinicaltrials.gov to learn more about Ocuphire's completed Phase 2 clinical trials and ongoing Phase 3 registration trials (NCT04620213 and NCT04638660), Phase 2 trial in presbyopia (NCT04675151) and soon to recruit Phase 2 trial in DR/DME (NCT04692688). For more information, please 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 product candidates, results of ongoing and future clinical trials, and commercialization and market opportunities. 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; (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, and (ix) the success and timing of commercialization of any of Ocuphire's product candidates. 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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Ocuphire Pharma, Inc.
Consolidated Balance Sheets
(in thousands, except share amounts and par value)

	As of December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,399	\$ 1,537
Prepays and other assets	1,269	149
Deferred costs	—	76
Total current assets	17,668	1,762
Property and equipment, net	14	22
Total assets	\$ 17,682	\$ 1,784
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 1,214	\$ 342
Accrued expenses	1,971	621
Convertible notes	—	4,977
Convertible notes from related parties	—	690
Premium conversion derivatives	—	2,714
Total current liabilities	3,185	9,344
Warrant liabilities	27,964	—
Total liabilities	31,149	9,344
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, par value \$0.0001; 10,000,000 and 625,000 shares authorized as of December 31, 2020 and 2019, respectively; no shares issued and outstanding at December 31, 2020 and 2019.	—	—
Common stock, par value \$0.0001; 75,000,000 and 5,000,000 shares authorized as of December 31, 2020 and 2019, respectively; 10,882,495 and 2,852,485 shares issued and outstanding at December 31, 2020 and 2019, respectively.	1	—
Additional paid-in-capital	19,207	495
Accumulated deficit	(32,675)	(8,055)
Total stockholders' deficit	(13,467)	(7,560)
Total liabilities and stockholders' deficit	\$ 17,682	\$ 1,784

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

	For the Year Ended December 31,	
	2020	2019
Operating expenses:		
General and administrative	\$ 2,818	\$ 1,820
Research and development	6,648	2,373
Acquired in-process research and development	10,502	—
Total operating expenses	19,968	4,193
Loss from operations	(19,968)	(4,193)
Interest expense	(6,847)	(1,409)
Fair value change in derivative and warrant liabilities	(1,486)	(499)
Gain on note extinguishment	3,672	—
Other income (expense), net	9	(68)
Loss before income taxes	(24,620)	(6,169)
Benefit (provision) for income taxes	—	—
Net loss	(24,620)	(6,169)
Other comprehensive loss, net of tax	—	—
Comprehensive loss	\$ (24,620)	\$ (6,169)
Net loss per share:		
Basic and diluted	\$ (5.28)	\$ (2.17)
Number of shares used in per share calculations:		
Basic and diluted	4,661,110	2,844,832