

April 19, 2022



# Ocuphire Appoints Jay Pepose, M.D., Ph.D., as Chief Medical Advisor and Announces Upcoming Presentations at ASCRS 2022 and Eyecelerator

**Three ASCRS presentations will feature data from Nyxol® clinical studies: second Phase 3 MIRA-3 trial (reversal of mydriasis) and Phase 2 VEGA-1 trial (presbyopia)**

FARMINGTON HILLS, Mich., April 19, 2022 (GLOBE NEWSWIRE) -- 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 appointment of Jay Pepose, M.D., Ph.D., as its Chief Medical Advisor. In addition, Dr. Jay Pepose, Dr. Ralph Chu, and Dr. Marguerite McDonald will deliver three presentations on Nyxol at the American Society of Cataract and Refractive Surgery (ASCRS) which will be held in Washington, D.C. from April 22-26, 2022. Ocuphire, represented by founder and CEO Mina Sooch, will also be featured in a spotlight refractive showcase at Eyecelerator @ASCRS 2022 on April 21<sup>st</sup>.

Jay Pepose said, "I am honored to take on the role of Chief Medical Advisor at Ocuphire, as I believe the company is on track to become a leader in the development of innovative treatment options for refractive and retinal diseases that affect a large majority of the aging and diabetic population. 2022 has the potential to be transformative for Ocuphire, with both Nyxol and APX3330 programs expected to deliver important clinical and regulatory milestones. I am very pleased to continue working with the highly talented Ocuphire team in an increased capacity. I look forward to advising the company to advance its two late-stage, small molecule drug candidates to address unmet medical needs of patients and sharing Ocuphire's clinical data with the medical community."

Dr. Pepose has served on Ocuphire's Medical Advisory Board since 2018 and Board of Directors since 2021. A specialist in refractive surgery and corneal and external diseases, he is the founder and Medical Director of the Pepose Vision Institute. He also founded the Midwest Corneal Research Foundation, now the Lifelong Vision Foundation, a non-profit organization focused on supporting research and education efforts in ophthalmology and providing vision treatment to underserved communities. He is a professor of clinical ophthalmology and visual sciences at Washington University School of Medicine in St. Louis and a consultant to the Centers for Disease Control and other large ophthalmic companies. Dr. Pepose has been involved in over 40 clinical research trials and has been the recipient of R-01 grant support from the National Eye Institute. He has served on the editorial boards of several prestigious journals, including the American Journal of Ophthalmology, Investigative

Ophthalmology & Visual Science (IOVS), Cornea, and The Journal of Refractive Surgery and has over 200 publications. Dr. Pepose is a recipient of the Cogan Award from the Association for Research in Vision and Ophthalmology (ARVO) and the Life Achievement Honor Award from the American Academy of Ophthalmology. Dr. Pepose received an A.B. and M.A. in neurophysiology from Brandeis University and completed the M.D. Ph.D. program at the University of California Los Angeles School of Medicine. He completed his ophthalmology residency at the Wilmer Institute at the Johns Hopkins Medical Center and his fellowship training at Georgetown University Medical Center.

Mina Sooch, MBA, Founder and CEO of OcuPhire Pharma, said, “We are thrilled to name Dr. Pepose as our Chief Medical Advisor. As a key member of our Medical Advisory Board and Board of Directors, Dr. Pepose has already been instrumental in guiding our late-stage clinical programs and engaging in regulatory interactions across all indications for Nyxol eye drops and oral APX3330. We are delighted that he will deepen his engagement with our operational and leadership teams at OcuPhire. Dr. Pepose’s appointment also comes at a strategic time for our company, as we look forward to important clinical and regulatory milestones, including a Phase 2 APX3330 readout for diabetic retinopathy in the second half of 2022, the initiation of the presbyopia Phase 3 program for both Nyxol and Nyxol with low-dose pilocarpine, and a potential NDA submission for Nyxol in reversal of mydriasis in late 2022.”

“We are excited to share three podium presentations on positive efficacy data with Nyxol from our second Phase 3 trial (MIRA-3), integrated safety data from the MIRA-2 and MIRA-3 registration trials, and positive single-agent Nyxol Phase 2 data at ASCRS. We are pleased to sponsor the ASCRS Beyond 20/20 educational series, which represents a great opportunity to connect with leading physicians and thought leaders,” added Mina Sooch.

### **[Eyecelerator @ASCRS 2022](#)**

Session: Spotlight Presentations- Refractive  
Date: Thursday, April 21, 2022, 10:30 AM – 11:15 AM  
Presenter: Mina Sooch, CEO  
Location: Renaissance Downtown Hotel, Washington, DC  
Conference Link: [Click here](#)

Eyecelerator is a one-day symposium representing a partnership between the American Academy of Ophthalmology (AAO) and the ASCRS with the goal of connecting entrepreneurs, investors, companies, and physicians to advance ophthalmic innovation.

### **[ASCRS Annual Meeting – April 22-26, 2022](#)**

Session: [Cornea Diagnostics and Studies](#)  
Title: The Safety of Phentolamine Ophthalmic Solution for Reversal of Pharmacologically Induced Mydriasis from Multiple Late-Stage Clinical Trials  
Presenter: Y. Ralph Chu, M.D.  
Date: Saturday, April 23, 2022  
Time: 1:40 PM – 1:45 PM EDT  
Location: Walter E. Washington Convention Center, Level 1, 143B  
Paper ID: 80618

Dr. Chu will present for the first time pooled safety results from the MIRA registration trials of Nyxol for reversal of pharmacologically-induced mydriasis (RM) completed to date, including results from the recently announced MIRA-3 Phase 3 trial. These results demonstrated a favorable safety and tolerability profile, consistent with over 10 completed Nyxol trials.

Session: [Presbyopia Correction: New Treatments and Studies](#)

Title: VEGA-1: Phentolamine Ophthalmic Solution as a Single Agent Improves Distance-Corrected Near Visual Acuity in Patients with Presbyopia

Presenter: Jay Pepose, M.D., Ph.D., ABO

Date: Monday, April 25, 2022

Time: 3:50 PM – 3:55 PM EDT

Location: Walter E. Washington Convention Center, Level 1, 143C

Paper ID: 80665

Dr. Pepose will present efficacy data from pre-specified endpoints in the multi-center, randomized, double-masked, placebo-controlled, VEGA-1 Phase 2 trial, which demonstrates that Nyxol as a single agent provided durable and statistically significant improvement in distance-corrected near visual acuity (DCNVA) with a favorable safety profile, particularly the absence of headaches, in 150 presbyopia patients. These results support the advancement to Phase 3 trials evaluating the efficacy of Nyxol alone and in combination with low dose pilocarpine for presbyopia.

Session: [Presbyopia Correction: New Treatments and Studies](#)

Title: MIRA-3: A 2nd Phase 3 Randomized Placebo-Controlled Trial of Phentolamine Ophthalmic Solution to Reverse Pharmacologically Induced Mydriasis

Presenter: Marguerite McDonald, M.D.

Date: Monday, April 25, 2022

Time: 4:05 PM – 4:10 PM

Location: Walter E. Washington Convention Center, Level 1, 143C

Paper ID: 81993

Dr. McDonald will present efficacy data, including new secondary endpoint results, from the completed MIRA-3 Phase 3 trial of Nyxol in RM. As announced recently, results showed that Nyxol had statistically significant improvements in reversing pharmacologically-induced mydriasis compared to placebo at all time points from 60 minutes to 24 hours. MIRA-2 and MIRA-3 represent two well-controlled, confirmatory Phase 3 clinical trials evaluating Nyxol in RM to support a planned NDA submission with the FDA in late 2022.

## **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 refractive and retinal indications. The company's lead product candidate, Nyxol<sup>®</sup> 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 several indications, including reversal of pharmacologically-induced mydriasis

(RM), presbyopia and dim light or night vision disturbances (NVD), and has been studied in 10 completed clinical trials. Ocuphire has reported positive topline data from MIRA-2 and MIRA-3, two registration trials for the treatment of RM, and recently completed enrollment in a pediatric safety trial (MIRA-4) in RM. Ocuphire also reported positive top-line data from a Phase 2 trial of Nyxol for treatment of presbyopia, both Nyxol as a single agent and Nyxol with low-dose pilocarpine (“LDP”) 0.4% as adjunctive therapy. The company recently completed enrollment in its Phase 3 study of Nyxol for NVD (LYNX-1). 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. The company recently announced the completion of enrollment in a Phase 2b clinical trial of APX3330 to treat DR/DME (ZETA-1). Please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) to learn more about Ocuphire’s recently completed Phase 3 registration trial in RM ([NCT05134974](https://clinicaltrials.gov/ct2/show/study/NCT05134974)), pediatric safety study in RM ([NCT05223478](https://clinicaltrials.gov/ct2/show/study/NCT05223478)), Phase 3 registration trial in NVD ([NCT04638660](https://clinicaltrials.gov/ct2/show/study/NCT04638660)), and Phase 2b trial in DR/DME ([NCT04692688](https://clinicaltrials.gov/ct2/show/study/NCT04692688)). Ocuphire previously completed the first Phase 3 registration trial in RM ([NCT04620213](https://clinicaltrials.gov/ct2/show/study/NCT04620213)) and Phase 2 trial in presbyopia ([NCT04675151](https://clinicaltrials.gov/ct2/show/study/NCT04675151)). 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. For more information, visit [www.ocuphire.com](http://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, timing and results in RM, presbyopia, NVD and DR/DME future clinical trials, as well as statements concerning the success and timing of planned regulatory filings and commercialization. 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.

## Ocuphire Contacts

Mina Sooch, President & CEO  
Ocuphire Pharma, Inc.  
[ir@ocuphire.com](mailto:ir@ocuphire.com)  
[www.ocuphire.com](http://www.ocuphire.com)

Corey Davis, Ph.D.  
LifeSci Advisors  
[cdavis@lifesciadvisors.com](mailto:cdavis@lifesciadvisors.com)



Source: Ocuphire Pharma