

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 09, 2023

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-51122
(Commission File Number)

26-2774444
(IRS Employer
Identification No.)

480 Pleasant Street
Watertown, Massachusetts
(Address of Principal Executive Offices)

02472
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 926-5000

(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 \$0.001	EYPT	The Nasdaq Global 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).

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 8.01 Other Events.

On November 9, 2023, EyePoint Pharmaceuticals, Inc. posted an updated investor presentation on its website at www.eyepointpharma.com. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation of EyePoint Pharmaceuticals, Inc. dated November 9, 2023
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

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.

EYEPOINT PHARMACEUTICALS, INC.

Date: November 9, 2023

By: /s/ George O. Elston
George O. Elston
Executive Vice President and Chief Financial Officer

Virtual KOL Event

November 9, 2023



Forward-Looking Statements

Various statements made in this presentation are forward-looking, within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about the sufficiency of our existing cash resources into 2025; our expectations regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration, non-proliferative diabetic retinopathy and diabetic macular edema; our potential to receive future payments from Alimera pursuant to our May 2023 sale and license agreement with Alimera; and our longer term financial and business goals and expectations, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; our ability to access needed capital; our ability to successfully manufacture sufficient quantities of YUTIQ® pursuant to our supply agreements with Alimera and Ocumension Therapeutics; the success of current and future license agreements, including our agreements with Alimera, Ocumension Therapeutics, Equinox Science and Beta Pharmaceuticals; termination or breach of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; effects of guidelines, recommendations and studies; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of our stock price; possible dilution; absence of dividends; the extent to which COVID-19 impacts our business and the medical community; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; and other factors described in our filings with the Securities and Exchange Commission. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

Featured Speakers



Jay Duker, M.D.
President and CEO

- >30 years experience managing retinal diseases in clinical practice
- Previous Director of the New England Eye Center (NEEC) and Professor and Chair of the Department of Ophthalmology at Tufts Medical Center and the Tufts University School of Medicine in Boston



David S. Boyer, M.D.

- Senior Partner at Retina-Vitreous Associates Medical Group
- Adjunct Clinical Professor of Ophthalmology at University of Southern California, Keck School of Medicine



David R. Lally, M.D.

- Retinal Surgeon at Baystate Medical Center
- Assistant Professor of Ophthalmology at the University of Massachusetts Medical School-Baystate
- Director of Retina Research Institute at New England Retinal Consultants

Agenda

PRESENTATION SPEAKER

Introductions	Jay Duker, M.D.
Presentation: EYP-1901 in Wet AMD	Jay Duker, M.D.
Key Opinion Leader Insights and Discussion	Jay Duker, M.D. David S. Boyer, M.D. David R. Lally, M.D.
Q&A	All
Closing Remarks	Jay Duker, M.D.



Company Overview

Jay Duker, M.D.

President and CEO



Committed to
developing
therapeutics to
improve the lives of
patients with
serious retinal
diseases

Pipeline represents multi billion-dollar opportunities using our bioerodible Durasert E™ intravitreal (IVT) delivery technology

- **EYP-1901** –vorolanib, a patented tyrosine kinase inhibitor (TKI)
 - Topline Phase 2 data in **wet AMD** anticipated in Dec 2023
 - Topline Phase 2 data in **NPDR** anticipated in Q2 2024
 - Phase 2 trial in **DME** planned to commence in Q1 2024
- **EYP-2301** –razuprotafib, a patented TIE-2 agonist for serious retinal diseases

Durasert® - proven, safe IVT drug delivery technology

- Routine in-office IVT injection
- Bioerodible and non-erodible formulations
- Safely administered to ~80,000 patient eyes across four FDA approved products with non erodible formulations

Strong Balance Sheet

- \$136.0M of cash and investments on September 30, 2023
- Cash runway into 2025

There is a Significant Need for More Durable Therapies in Wet AMD



1 • Many patients with wet AMD are chronically undertreated

- >80% of Retina Specialists say undertreatment is due to patient noncompliance, scheduling limitations or provider preference for less frequent dosing¹



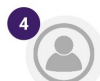
2 • Current “treat and extend” protocol still places significant burden on physicians and patients

- Chronic disease treated with short acting anti-VEGF biologics




3 • A delay in care/missed visit can result in vision loss

- A delay in treatment of only 5.34 weeks resulted in vision loss²



4 • An aging population means significantly more injections in a patient’s lifetime

- Current anti-VEGF treatments are dosed on average every two months in the United States³



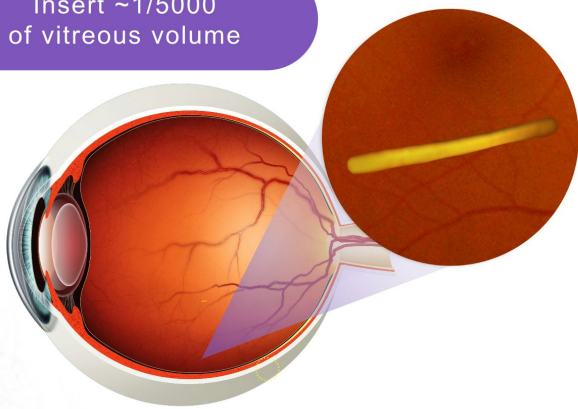
EYP-1901 a potential
sustained delivery 6-
month treatment for
wet AMD

Jay Duker, M.D.
President and CEO



EYP-1901 Delivers VEGF Receptor Binding Vorolanib In Durasert E™

Insert ~1/5000
of vitreous volume

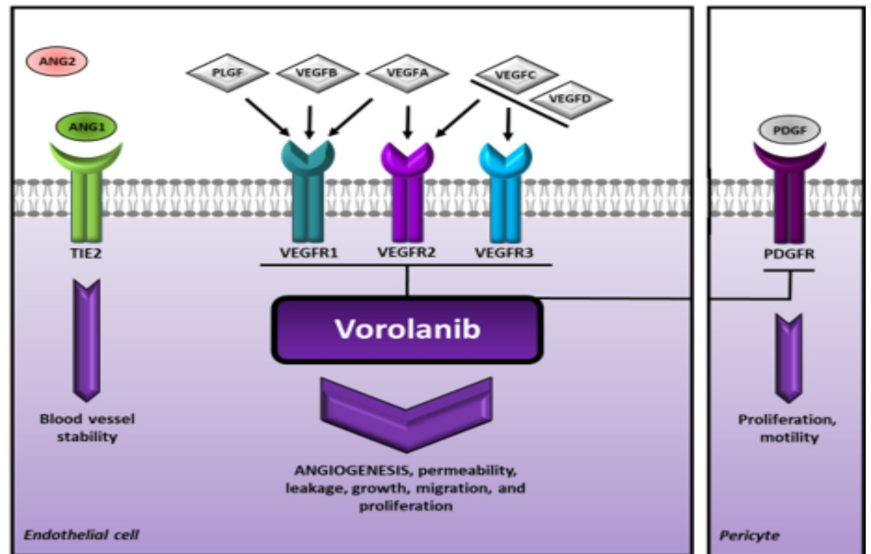


- Vorolanib – a potential new MOA to the treatment of wet AMD
- Sustained release with zero order kinetics blocking all isoforms of VEGF
- Immediately bioavailable, featuring an initial burst of drug followed by near constant zero order kinetic release for approximately 9 months
- Positive safety results and efficacy data in wet AMD from Phase 1 DAVIO clinical trial
- Ongoing positive safety through October 1, 2023 in ongoing Phase 2 clinical trials with all patients at least 4-months post injection
- Shipped and stored at ambient temperature

Vorolanib Brings a New MOA to the Treatment of VEGF-Mediated Retinal Diseases by Blocking all Isoforms of VEGF as well as PDGF

Vorolanib is a novel molecule

- Potent and selective pan-VEGF receptor inhibitor
- Demonstrated neuroprotection in a validated retinal detachment animal model
- Blocks PDGF which may lead to antifibrotic effects
- Reduced off-target binding and does not inhibit TIE-2 at clinically relevant doses



DAVIO Phase 1 Clinical Trial in Wet AMD Enrollment Summary

- Multicenter, open-label, single-injection dose-escalation
- Enrolled patients previously treated (8.6 mean injections previous 12 months)
- Fluid status at entry was not an exclusion criterion
- Minimum of three anti-VEGF injections in previous 6 months
- Single intravitreal aflibercept followed by single EYP-1901 injection
- Primary endpoint: Safety (ocular & non-ocular TEAEs through month 12)
- Secondary endpoint: Change in BCVA & CST; supplemental anti-VEGF therapy

EYP-1901 Phase 1 DAVIO Clinical Trial Met All Objectives And Informed Phase 2 Design

FAVORABLE SAFETY PROFILE

- No ocular SAEs reported
- No drug-related systemic SAEs reported
- Ocular AEs – majority are mild and expected with IVT administration

POSITIVE EFFICACY & DURABILITY

Endpoint (6-month)	DAVIO	DAVIO Subgroup Analysis*
Change in BCVA	-2.5	-0.4
Reduction in Treatment Burden	75%	92%
Percent of Eyes Supplement-Free	53%	67%
OCT	-3.4 μm	-1.0 μm

EYP-1901 Is Positioned As A Potential Maintenance Therapy In Wet AMD

- **Treat** wet AMD patients with anti-VEGF of choice to reach desired “dry” outcome and maximize visual improvement
- **Maintain** with EYP-1901, a new MOA with sustained delivery and zero order kinetics for six-months or longer providing physicians and patients the potential flexibility to reduce the number of visits without sacrificing visual outcomes
- **Supplement** with current anti-VEGF biologic, if needed

Based on DAVIO Phase 1 outcomes, we believe the majority of patients may be maintained visually and anatomically with EYP-1901 alone

EYP-1901 May Provide Greater Flexibility in Managing Patients

- Tailor dosing schedule to patient needs
- Manage the disease with different, complementary MOAs
- Potentially treat a chronic disease with both short- and long-acting drugs
- Optimize patient visit and flow



EYP-1901 in Wet AMD

DAVIO 2 Clinical Trial Update



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The DAVIO 2 clinical trial was designed to support initiation of Phase 3 clinical trials based on a Type C meeting with FDA

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Objective: Evaluate efficacy and safety of a single injection of two doses of EYP-1901

Key changes in enrollment from DAVIO trial

- CST below 350um at screening to exclude poor responders to standard of care treatment **but still allows for fluid**
- Response to recent (2-5 weeks) anti-VEGF treatment
- No significant intraretinal fluid (IRF)

Anti-VEGF supplement criteria tightened for visual acuity in DAVIO 2

- 5 letter loss with 75 microns of new fluid
- Other criteria
 - 10 letter loss due to wet AMD
 - 100 microns new fluid x 2 visits
 - New heme from wet AMD
 - Investigator discretion

Primary outcome is difference in change in BCVA from Day 1 to Week 28 and 32 (blended)

EYP-1901 DAVIO 2 Clinical Trial Is A Randomized, Double-Masked, Aflibercept Controlled* With A Single EYP-1901 Treatment At Two Doses



- REQUIRED AFLIBERCEPT INJECTION VISIT
- VISIT SCHEDULED
- EYP-1901 DOSE
- SHAM INJECTION FOR MASKING

EYP-1901 Continues to Show a Favorable Safety Profile Across Multiple Clinical Trials Through October 1, 2023

Summary:

DAVIO (Phase 1): 17 patients treated

DAVIO 2 (Phase 2): ~105 patients treated

PAVIA (Phase 2): ~51 patients treated

~173 treated patients with a minimum of four months post EYP-1901 injection with no drug-related ocular or systemic SAE's

Masked Patient Demographic Reflects A More Stable Population in DAVIO 2 Compared to the DAVIO Phase 1 Trial

Phase 1 DAVIO Baseline Characteristics (N = 17)*

Mean age, years	77
Female, %	76%
Mean BCVA, ETDRS letters	69
Mean CST, μm	299

Phase 2 DAVIO 2 Baseline Characteristics (N = 160)**

Mean age, years	76
Female, %	62%
Mean BCVA, ETDRS letters	74
Mean CST, μm	265

Outcome Scenarios for DAVIO 2 Primary Endpoint of Non-Inferior Change in BCVA to Aflibercept

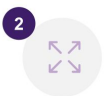
- FDA defined the lower bound for non-inferiority as -4.5 letters
- Outcome scenario ranges for EYP-1901 BCVA versus aflibercept control:
 - **Superior:** >0.0 letter VA change and numerically and/or statistically superior
 - **Outstanding*:** -1.4 to 0.0 letter VA change and likely statistically non-inferior
 - **Great:** -1.5 to -2.9 letter VA change and possibly statistically non-inferior
 - **Revisit:** -4.0 letter or worse VA change

DAVIO 2 Outcomes: Lower Limit Ranges to Support Potential Phase 3 Trials

Primary/Critical Endpoints



- < -3 letters change in visual acuity difference between treatment arms and control¹



- Favorable safety profile



- 50% or better reduction in treatment burden



- 50% or better percent of eyes supplement-free up to six months



- Stable anatomical outcome as measured by OCT (within ~30 microns)

Secondary Endpoints

Reduction in Treatment Burden is an Important Secondary Outcome Given the Unmet Need in wet AMD for More Durable Therapies

- Treatment burden = Number of injections an eye receives for the 24-week period following EYP-1901 dosing or sham injection in control arm
- Treatment burden will be assessed and reported in two ways:
 - **Prospectively** against the aflibercept control
 - **Retrospectively** against the mean number of treatments prior to enrollment
- Market research suggests a reduction in treatment burden of 50% or greater in one or both arms of EYP-1901 could provide physicians the flexibility to reduce the number of visits without sacrificing visual outcomes



Key Opinion Leader Insights and Discussion

EYP-1901 in wet AMD and Topline
Data Considerations for the DAVIO 2
Clinical Trial





Q&A



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Virtual KOL Event

November 9, 2023

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