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) May 28, 2024

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-51122**	**26-2774444**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
480 Pleasant Street **Watertown, Massachusetts**		**02472**
(Address of Principal Executive Offices)		**(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 May 28, 2024, 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.

Exhibit No.	Description
99.1	Investor Presentation of EyePoint Pharmaceuticals, Inc. dated May 28, 2024
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: May 28, 2024

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

Exhibit 99.1

Investor Presentation

May 2024

Legal Disclaimers

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 through topline data for Phase 3 clinical trials for DURAVYU™ in wet AMD; our expectations regarding the timing and clinical development of our product candidates, including DURAVYU and EYP-2301; the potential for DURAVYU as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration, non-proliferative diabetic retinopathy and diabetic macular edema; 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; 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 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.

EYEPOINT PHARMACEUTICALS

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

Pipeline represents potential multi billion-dollar opportunities

- **DURAVYU™ (vorolanib intravitreal insert)** – vorolanib, a selective and patented TKI in Durasert E™
  - First pivotal phase 3 trial in **wet AMD** on-track to **initiate** in 2H 2024
  - Positive topline DAVIO 2 Phase 2 data in **wet AMD**
  - PAVIA trial in **NPDR** demonstrated stable or improved DRSS scores and continued favorable safety; 12-month data expected Q3 2024
  - Phase 2 clinical trial in **DME** underway
- **EYP-2301 –** razuprotafib, a patented TIE-2 agonist for serious retinal diseases in Durasert E™

Durasert® - proven, safe IVT drug delivery technology

- Bioerodible Durasert E™ and non-erodible formulations
- Safely administered to thousands of patient eyes across four FDA approved products with non-erodible formulations

Strong Balance Sheet

- **$299M** of cash and investments on March 31, 2023
- Cash runway through Phase 3 wet AMD pivotal trials topline data in 2026

DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.
IVT, intravitreal injection

Potential Multi Billion-Dollar Product Opportunities Leveraging Innovative Drug Delivery Technology, Bioerodible Durasert E™

Durasert E™ Programs	Indication	Discovery	Pre-Clin	Phase 1	Phase 2	Phase 3	Next Milestone
DURAVYU (EYP-1901) – vorolanib in Durasert E™ (tyrosine kinase inhibitor)	Wet AMD						First Phase 3 Trial 2H 2024
	NPDR						12-month data Q3 2024
	DME						Topline data in Q1 2025
EYP-2301 – razuprotafib in Durasert E™ (TIE-2 agonist)	serious retinal diseases						Pre-clin tox and PK data
Complement inhibition	GA						Potential product candidate in 2024

non-clinical *trial underway*

wet AMD, wet age-related macular degeneration; EOP2, End of Phase 2; FPI, first patient in; NPDR, non-proliferative diabetic retinopathy; DME, diabetic macular edema; GA, geographic atrophy

EyePoint Pharmaceuticals

Durasert - Intravitreal Sustained-Release Drug Delivery

TECHNOLOGY
DURASERT®

Safe, Sustained IVT Drug Delivery

- Delivered via a standard in-office IVT injection
- Continuous, stable release of drug
- Zero-order kinetics

Durasert E™: bioerodible

- Drug embedded within a bioerodible matrix
- No polyimide shell
- Designed to deplete drug load before matrix fully erodes
  - DURAVYU™

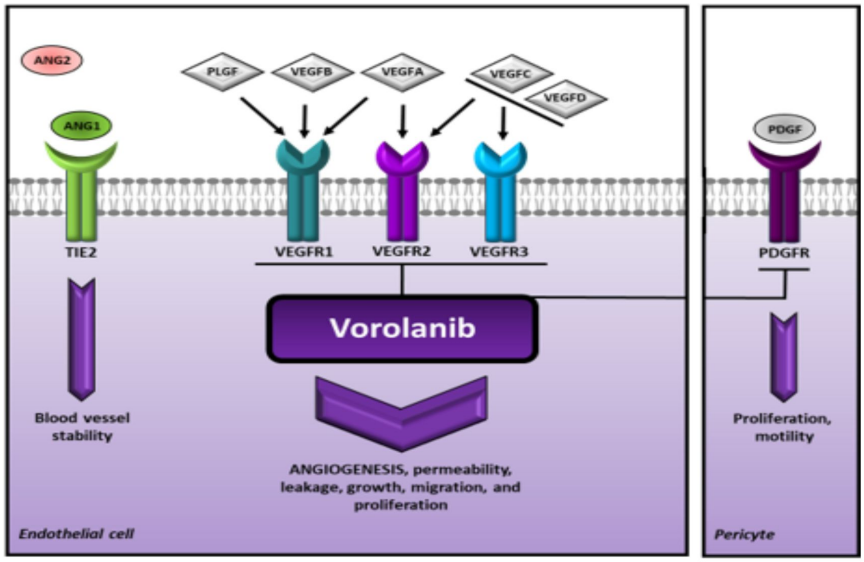
Durasert®: non-erodible

- Drug embedded within a bioerodible matrix covered with non-erodible polyimide shell:
  - YUTIQ®[1]
  - ILUVIEN®[1]
  - RETISERT®[2]
  - VITRASERT®[2]

1- licensed to Alimera; 2 – licensed to Bausch and Lomb

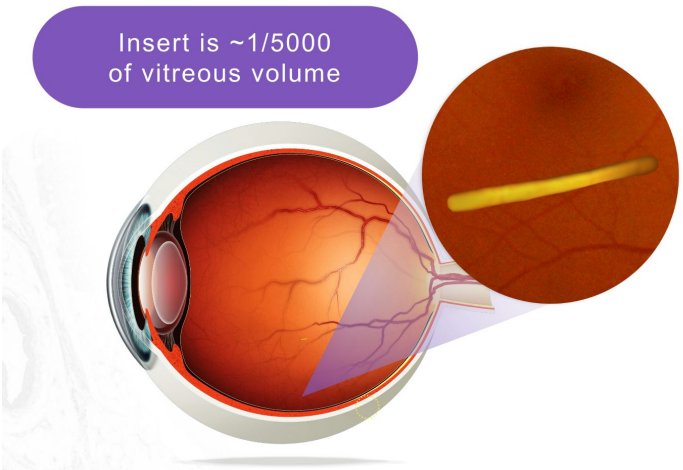
Vorolanib Brings a Potential New MOA to the Treatment of VEGF-Mediated Retinal Diseases by Inhibiting all Isoforms of VEGF and PDGF

- Potent and selective **pan–VEGF** receptor inhibition
- Composition of matter patent into 2037
- Demonstrated **neuroprotection** in a validated retinal detachment animal model
- Inhibits PDGF which may lead to **antifibrotic** benefit
- Reduced off-target binding - does not inhibit TIE-2 at clinically relevant doses[1]



1. Sophie Bakri, M.D., et al. PLOS ONE, *Vorolanib, sunitinib, and axitinib: A comparative study of vascular endothelial growth factor receptor inhibitors and their anti-angiogenic effects*, 2024.
VEGF(R), vascular endothelial growth factor (receptor); PDGF(R), platelet-derived growth factor (receptor); TIE-2, tyrosine-protein kinase receptor

DURAVYU: VEGF Receptor Binding Vorolanib In Bioerodible DurasertE™



- **Positive efficacy** data in wet AMD from Phase 1 DAVIO and Phase 2 DAVIO 2 clinical trials
- Favorable safety profile **with no ocular or systemic DURAVYU-related SAEs** reported in ongoing Phase 2 clinical trials
- **Immediately bioavailable** featuring an initial burst of drug followed by zero order kinetics release
- Vorolanib fully eluted prior to complete bioerosion of the matrix to **control release** and allow **redosing** regimen
- Delivered in the physician office via **routine intravitreal injection**
- Shipped and stored at **ambient temperature**

VEGF – vascular endothelial growth factor: AMD – age related macular degeneration;

EyePoint PHARMACEUTICALS

Phase 2 DAVIO 2 Clinical Trial Topline Results in wet AMD

A NON-INFERIORITY TRIAL VERSUS AN AFLIBERCEPT CONTROL

EyePoint Pharmaceuticals

The DAVIO 2 Clinical Trial in wet AMD

A non-inferiority trial evaluating two doses of DURAVYU against an aflibercept control as a potential 6-month maintenance therapy

Design:
Multi-center, randomized, double-masked trial in patients with previously treated wet AMD

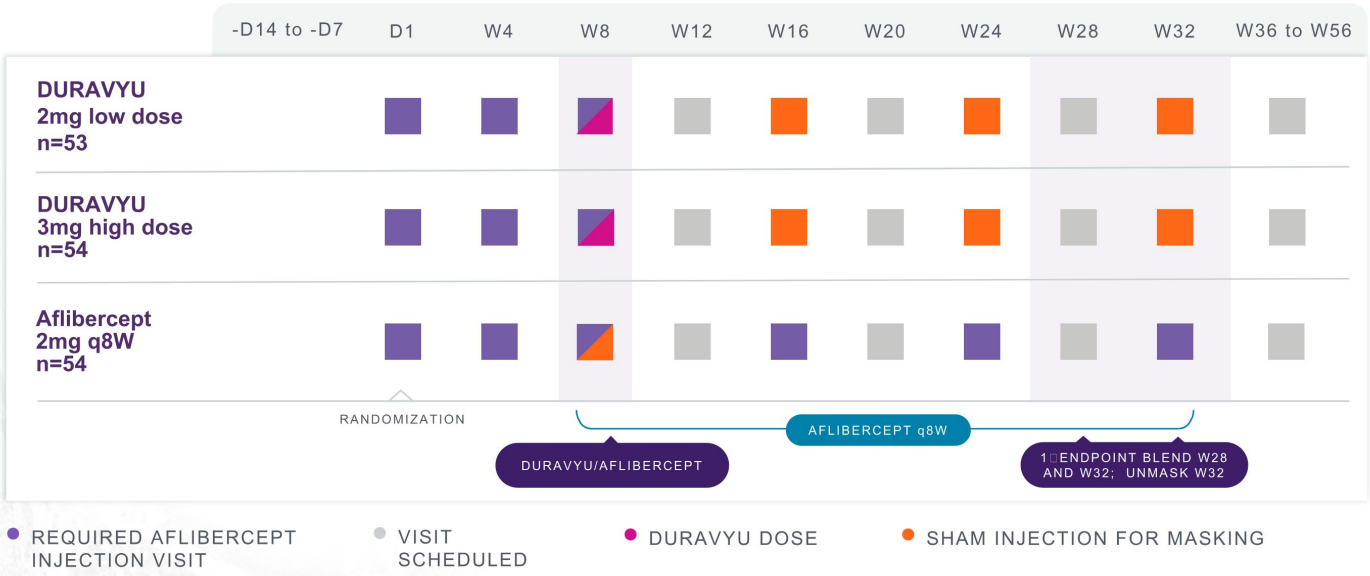
Primary outcome:
Difference in mean change in BCVA from Day 1 to Week 28 and 32 (blended)

Key secondary endpoints:
- Safety
- Reduction in treatment burden
- Percent of eyes supplement-free up to six months
- Anatomical results

Anti-VEGF supplement criteria:
- 5 letter loss with 75 microns of new fluid
- 10 letter loss due to wet AMD
- 100 microns new fluid x 2 visits
- New retinal hemorrhage from wet AMD
- Investigator discretion

EyePoint Pharmaceuticals

DAVIO 2 Clinical Trial is Randomized, Double-Masked, Aflibercept Controlled* with a Single DURAVYU Treatment at Two Doses



*Aflibercept on-label control required by FDA

EyePoint PHARMACEUTICALS

DAVIO 2 Patient Baseline Characteristics Well Balanced Across Arms

	Aflibercept 2mg q8W (n=54)	DURAVYU 2mg (n=50)	DURAVYU 3mg (n=52)
Mean age, years (range)	75.9 (52-93)	76.4 (61-93)	75.4 (56-89)
Female, %	53.7%	64.0%	67.3%
Mean BCVA, ETDRS letters (range)	73.4 (41-85)	73.9 (52-84)	74.9 (46-85)
Mean CST, µm (range)	265.7 (178-348)	267.0 (192-400)	262.9 (186-345)
Median length of time for wet AMD diagnosis prior to screening, months (range)	28.1 (2.4-273.8)	24.3 (2.4-168.1)	28.1 (2.4-145.3)
Mean # of injections normalized to 12 months prior to screening (range)*	9.5 (2-12)	10.2 (2-13)	10.0 (2-13)

Heavily pre-treated group

PRELIMINARY DATA – PENDING FINAL ANALYSIS

AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; VEGF, vascular endothelial growth factor.

EyePoint Pharmaceuticals

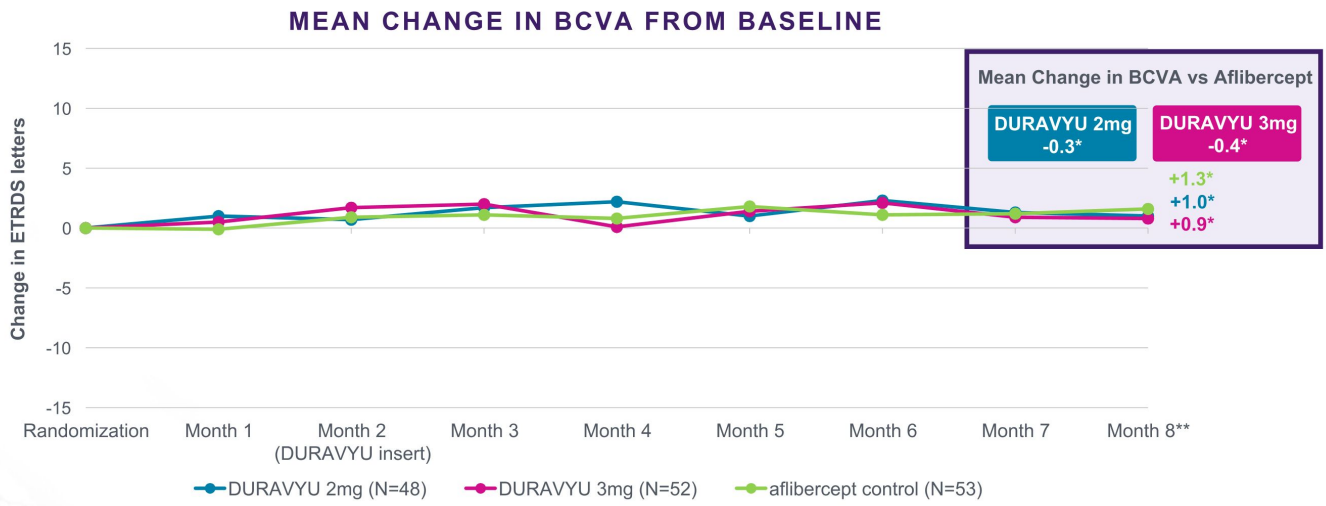
DURAVYU Phase 2 DAVIO 2 Clinical Trial in Wet AMD Met All Primary and Secondary Objectives

Endpoint	Endpoint Achieved	2mg Arm	3mg Arm
Primary: Non-inferior change in BCVA vs. aflibercept	✓	- 0.3 letters	- 0.4 letters
Secondary: Favorable safety profile[1]	✓	No DURAVYU-related SAEs	
Secondary: Reduction in treatment burden vs. 6 mos prior	✓	89%	85%
Secondary: Reduction in treatment burden vs. aflibercept	✓	83%	79%
Secondary: Supplement-free up to 6 months	✓	65% 88% of eyes had 0 or only 1 supplemental injections	64% 83% of eyes had 0 or only 1 supplemental injections
Secondary: Anatomical control vs. aflibercept	✓	+9.7um	+5.2um

1. As of November 7, 2023 data cut
PRELIMINARY DATA – PENDING FINAL ANALYSIS

EYEPOINT PHARMACEUTICALS

DURAVYU was Statistically Non-Inferior in Change in BCVA Compared to the Aflibercept Control (95% CI)

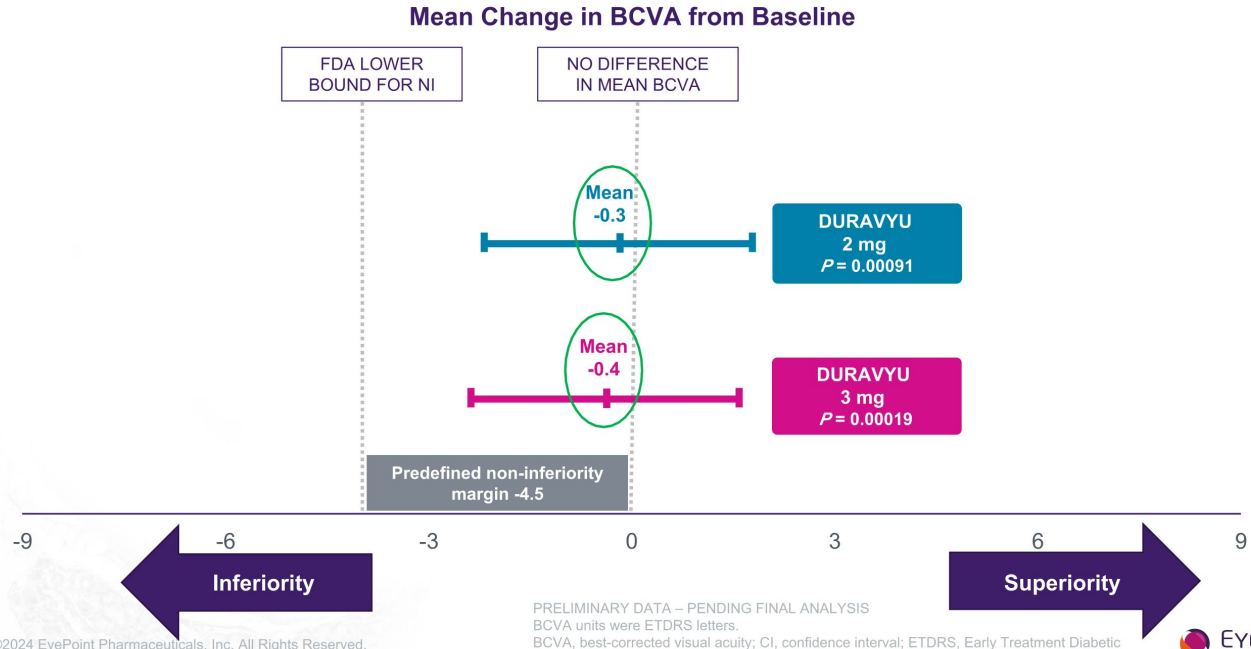


In the Pulsar trial, HD Eylea (16-week 8mg arm) change in BCVA vs. 2mg Eylea was -1.4 letters[1]

*Blended week 28 and week 32 change vs. baseline
**Month 8 represents 6 months after DURAVYU injection
CI, Confidence Interval
PRELIMINARY DATA – PENDING FINAL ANALYSIS

1 – AAO 2022 presentation, Paolo Lanzetta, on behalf of the PULSAR study investigators

95% Confidence Intervals Showed Statistical Non-Inferiority for Primary Endpoint with DURAVYU vs Aflibercept Control



PRELIMINARY DATA – PENDING FINAL ANALYSIS
BCVA units were ETDRS letters.
BCVA, best-corrected visual acuity; CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; FDA, Food and Drug Administration; q16W, every 16 weeks.

DURAVYU Demonstrated a Favorable Safety Profile in the Phase 2 DAVIO 2 Clinical Trial[1]

- No reported DURAVYU-related ocular or systemic SAEs
  - Four ocular SAEs reported in a study eye – none deemed DURAVYU related[2]
- >97% of AEs reported were mild (Grade 1 or 2) and generally expected with IVT
- No insert migration into the anterior chamber
- No retinal occlusive vasculitis
- Low patient discontinuation rate of 4% up to week 32
  - No discontinuations were related to DURAVYU treatment

SAE, serious adverse event; AE, adverse event; IVT, intravitreal injection
PRELIMINARY DATA CUT– PENDING FINAL ANALYSIS

1- As of November 7, 2023 data cut
2- as deemed by the investigator

EYEPOINT PHARMACEUTICALS

DURAVYU Continues to Show a Favorable Safety Profile Across Multiple Clinical Trials

Summary:

DAVIO (Phase 1):	17 patients treated
DAVIO 2 (Phase 2)[1]:	102 patients treated
PAVIA (Phase 2)[1]:	51 patients treated

170 treated patients with a minimum of eleven months post DURAVYU injection with no DURAVYU-related ocular or systemic SAE's

Data as of April 25, 2024
1-Data are preliminary pending study completion and final report.
SAE, serious adverse event

EyePoint PHARMACEUTICALS

Clinically Meaningful Reduction in Treatment Burden Supports DURAVYU as a Maintenance Treatment For Wet AMD

	DURAVYU 2mg	DURAVYU 3mg
Mean number of injections week 8 through week 32	0.55	0.71
Mean number of injections 6 months prior to screening*	5.07	4.98
Reduction in treatment burden vs. 6 months prior (%)	**89%**	**85%**

*Normalized
PRELIMINARY DATA – PENDING FINAL ANALYSIS

DURAVYU Demonstrated a Meaningful Reduction in Treatment Burden vs. the Aflibercept Control Arm

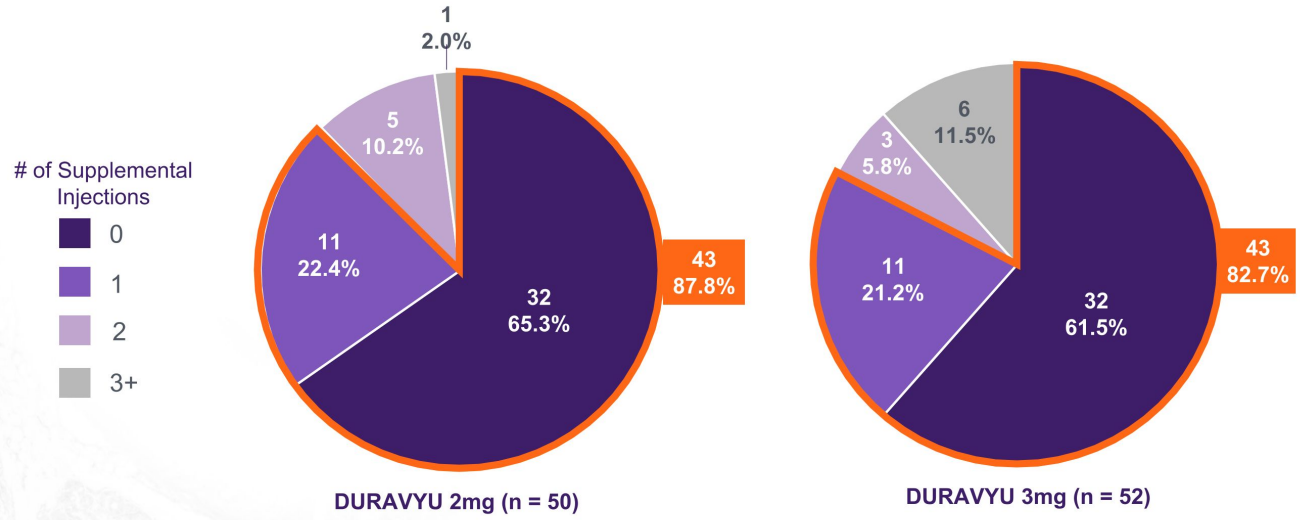
	DURAVYU 2mg	DURAVYU 3mg	Aflibercept 2mg q8W
Mean number of injections week 8 through week 32	0.55	0.71	3.32
Reduction in treatment burden vs. aflibercept control (%)	**83%**	**79%**	**NA**

PRELIMINARY DATA – PENDING FINAL ANALYSIS.

EyePoint PHARMACEUTICALS

DURAVYU Demonstrated Clinically Meaningful Supplement-Free Rates with ≥83% of Eyes Receiving 0-1 Anti-VEGF Supplemental Injections

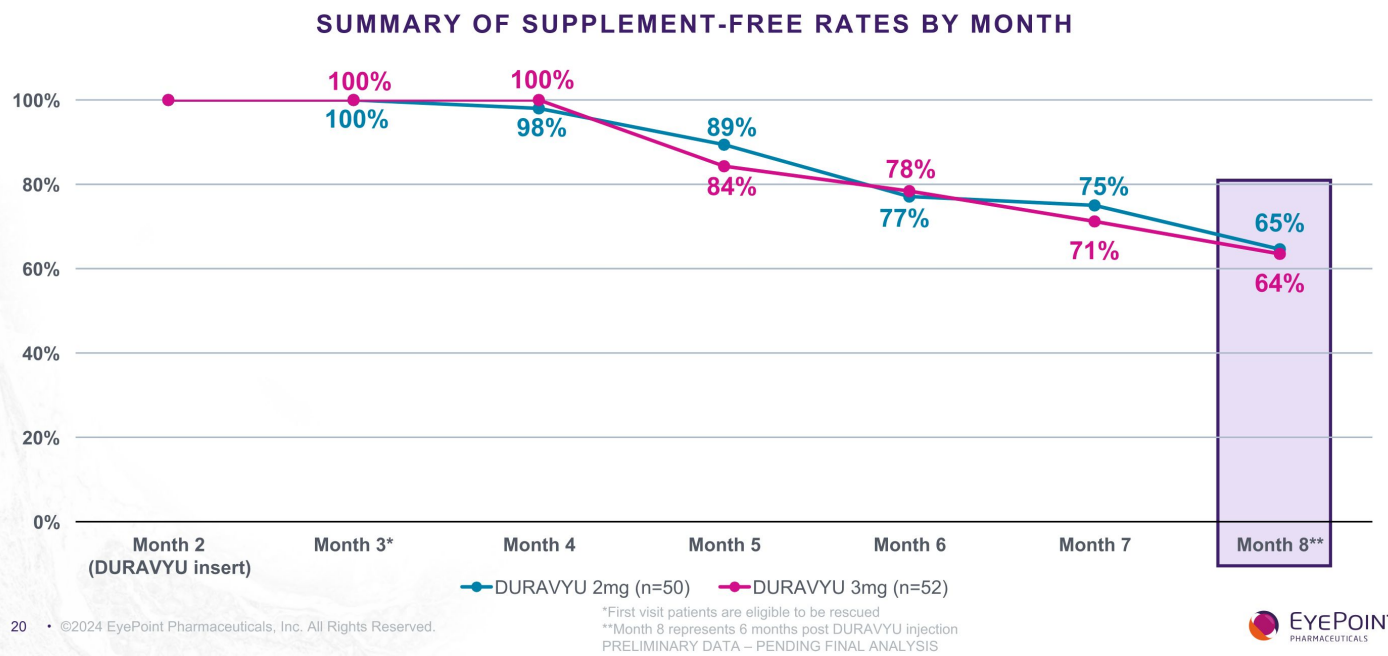
NUMBER OF SUPPLEMENTAL INJECTIONS SIX MONTHS AFTER DURAVYU INSERT



*PRELIMINARY DATA – PENDING FINAL ANALYSIS

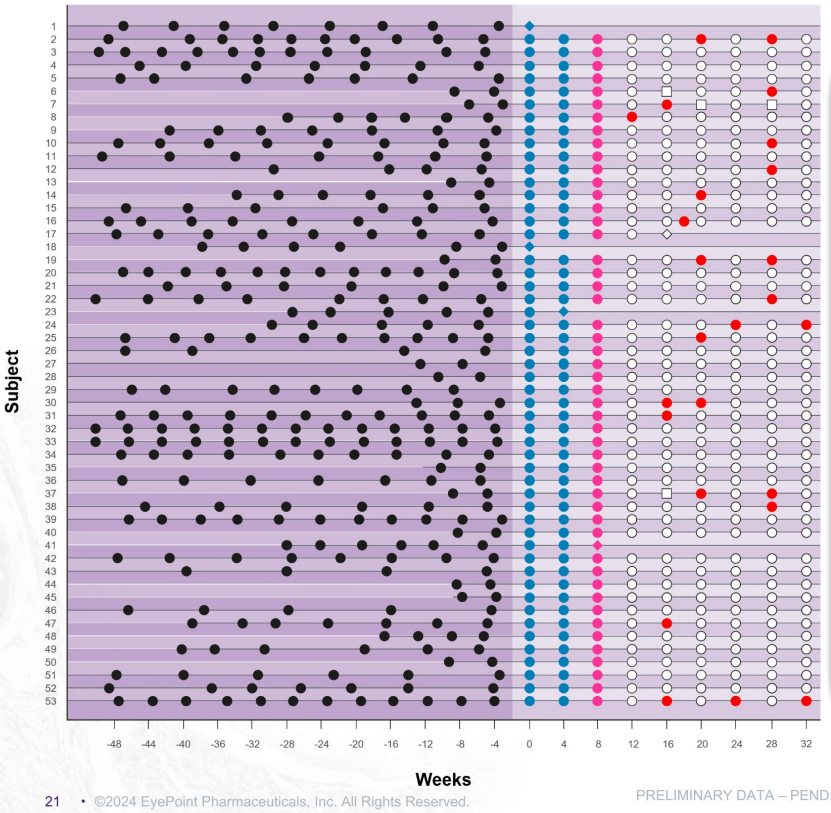
EYEPOINT PHARMACEUTICALS

Nearly Two-Thirds of Eyes Treated with DURAVYU were Supplement-Free up to Six Months After a Single Injection



*First visit patients are eligible to be rescued
**Month 8 represents 6 months post DURAVYU injection
PRELIMINARY DATA – PENDING FINAL ANALYSIS

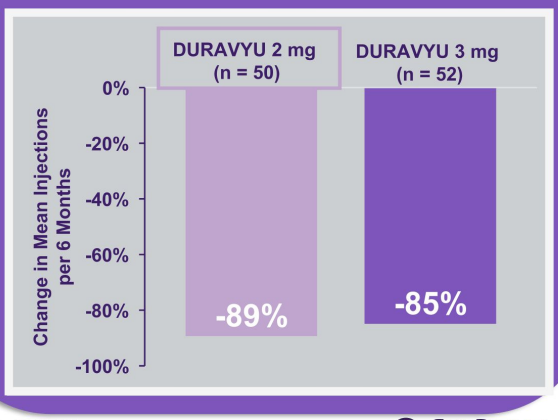
EyePoint Pharmaceuticals



DURAVYU 2mg Dose Reduced Treatment Burden by 89% Compared to Prior 6 Months

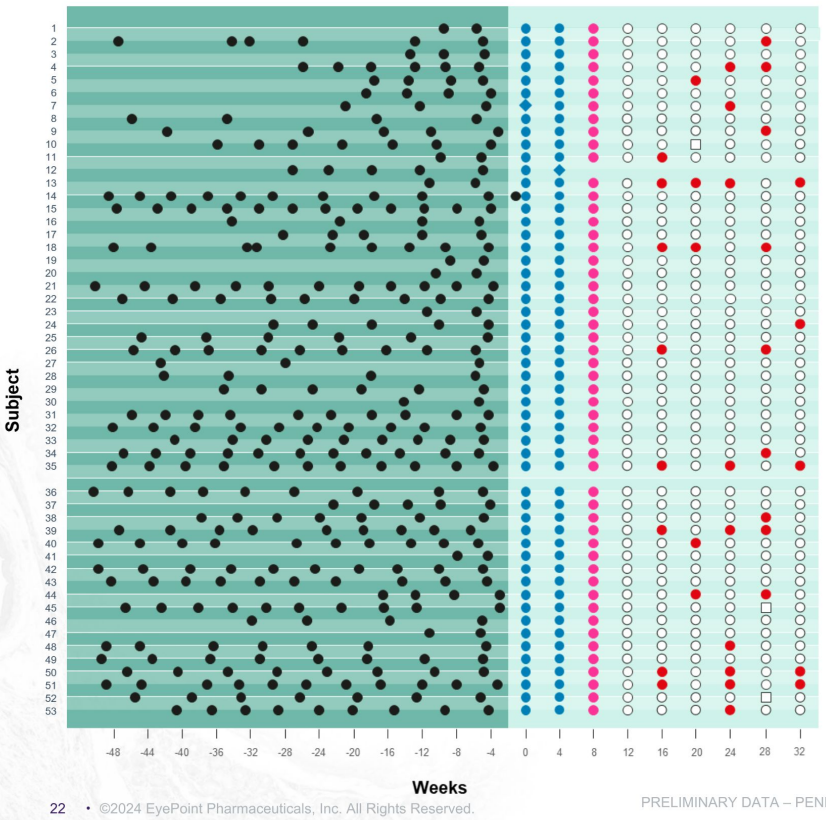
Injections in year prior and during the DAVIO 2 trial

- Anti-VEGF injection
- Aflibercept loading dose
- Aflibercept + DURAVYU
- No injection
- Missed Visit
- Supplemental injection



PRELIMINARY DATA – PENDING FINAL ANALYSIS

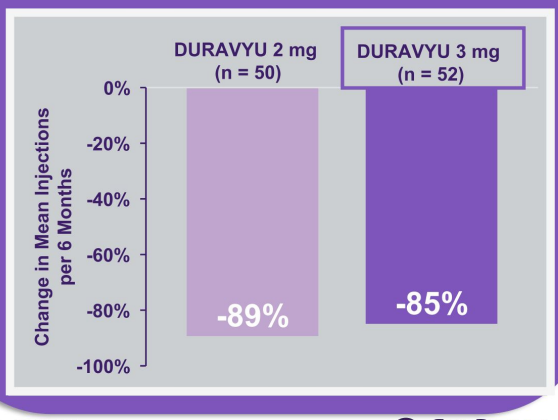
EYEPOINT PHARMACEUTICALS



DURAVYU 3mg Dose Reduced Treatment Burden by 85% Compared to Prior 6 Months

Injections in year prior and during DAVIO 2 trial

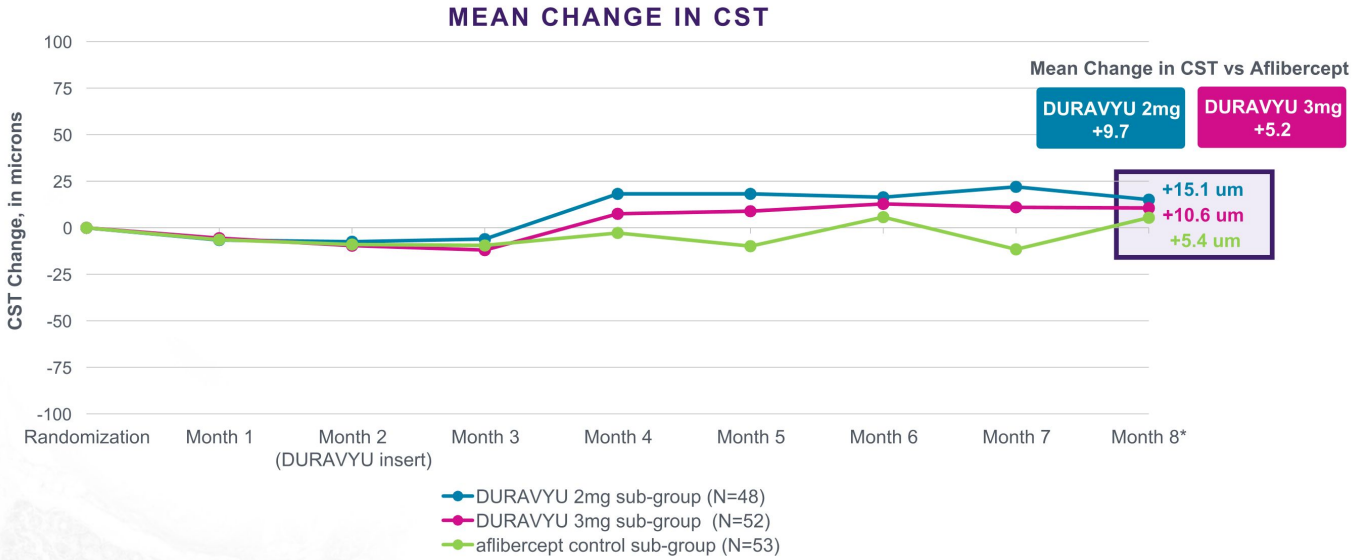
- Anti-VEGF injection
- Aflibercept loading dose
- Aflibercept + DURAVYU
- No injection
- Missed Visit
- Supplemental injection



PRELIMINARY DATA – PENDING FINAL ANALYSIS

EYEPOINT PHARMACEUTICALS

Data from DAVIO 2 Suggests Strong Anatomic Control with OCT Change Below 10 microns at 6-Months Compared to the Aflibercept Control



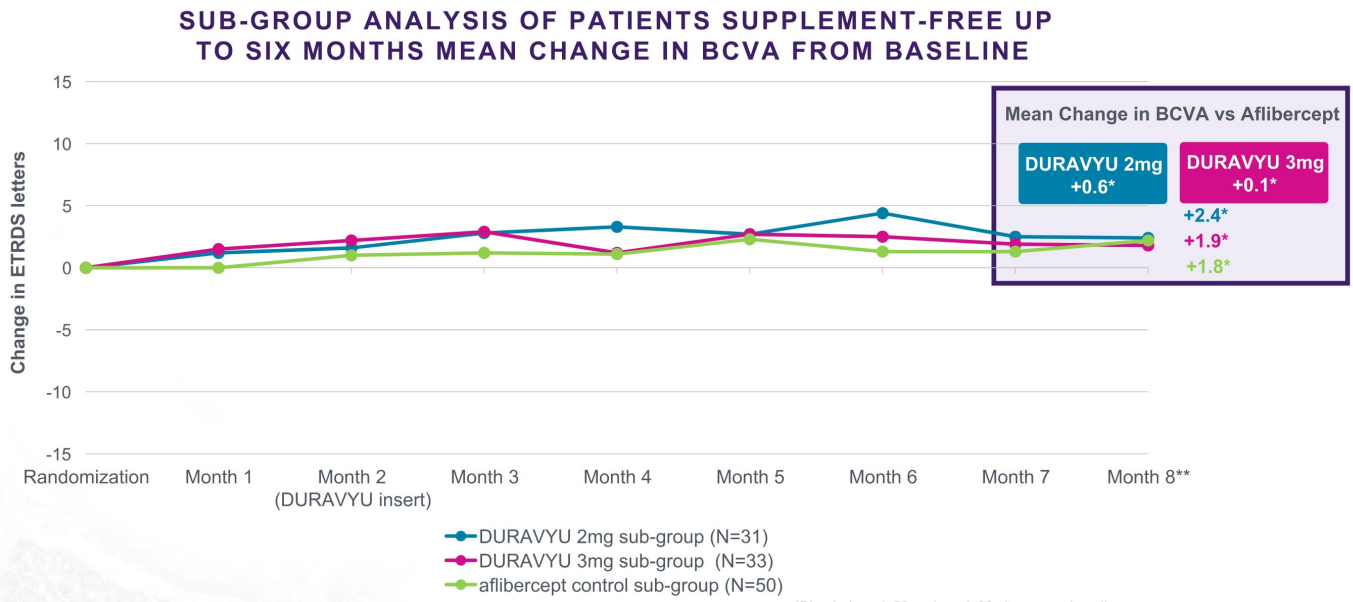
*Month 8 represents 6 months after first DURAVYU injection
PRELIMINARY DATA – PENDING FINAL ANALYSIS

Phase 2 DAVIO 2 Trial in Wet AMD

Sub-Group Analysis of Patients Anti-VEGF Supplement-Free Up to 6 Months

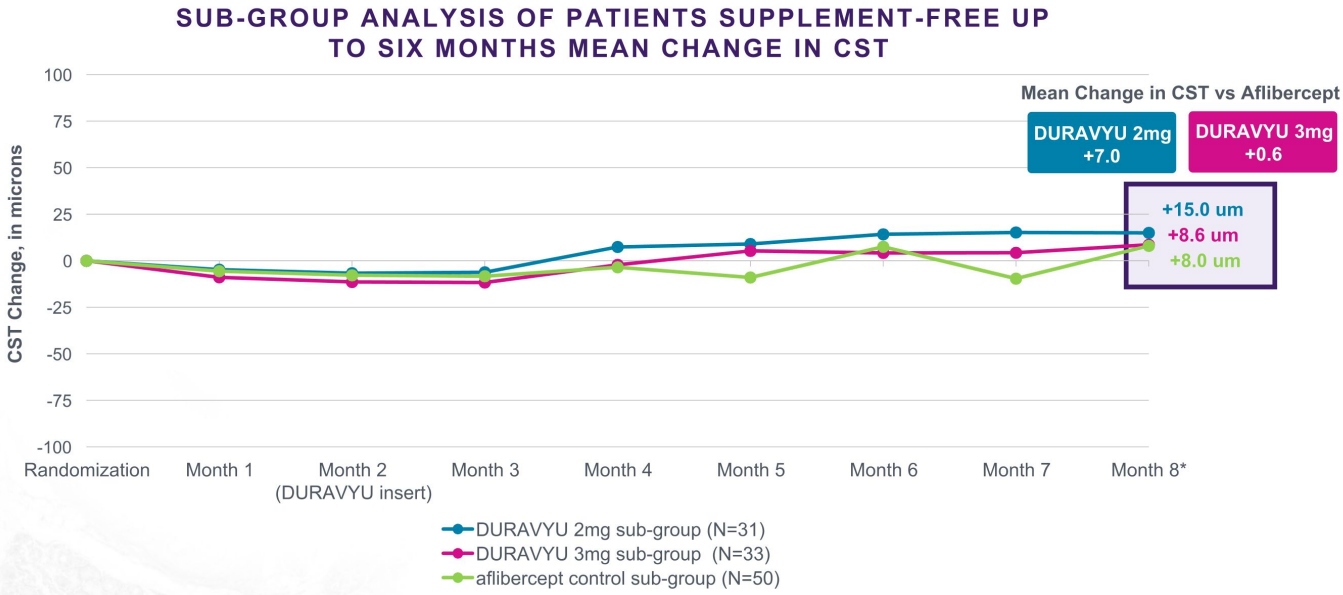
EyePoint Pharmaceuticals

DURAVYU Demonstrated Numerical Superiority in Change in BCVA in Sub-Group Analysis of Patients Supplement-Free Up to 6-Months



*Blended week 28 and week 32 change vs. baseline
**Month 8 represents 6 months after DURAVYU injection
PRELIMINARY DATA – PENDING FINAL ANALYSIS

Strong Anatomic Control in Patients Supplement Free Up to 6-Months with OCT Change Below 10 microns Compared to the Aflibercept Control



*Month 8 represents 6 months after first DURAVYU injection
PRELIMINARY DATA – PENDING FINAL ANALYSIS

Phase 3 Pivotal Trials Design*

NON-INFERIORITY VERSUS AN AFLIBERCEPT CONTROL

EYEPOINT PHARMACEUTICALS

*Pending final FDA review.

DURAVYU Non-Inferiority Phase 3 Clinical Trials Design in Wet AMD

- Design of the Phase 3 trials were informed by previous **Type C meeting with FDA** and **positive DAVIO 2 data** with additional considerations for potential FDA approval and product label.
- **Positive EOP2** meeting with FDA **completed in April 2024**; waiting for final FDA review*
- Key trial design elements agreed upon with FDA:
  - Two pivotal, **non-inferiority trials** vs. aflibercept control
  - **12-month** primary efficacy endpoint (blended) – basis of NDA submission
  - DURAVYU **re-dosing** at six-month intervals – 4 total doses
  - Masking strategy

We remain on-track to initiate the LUGANO trial (US) in 2H 2024
with LUCIA trial (US/OUS) to follow.

*Timing TBD based on extenuating circumstances with the interim FDA Division of Ophthalmology leadership required for sign-off.

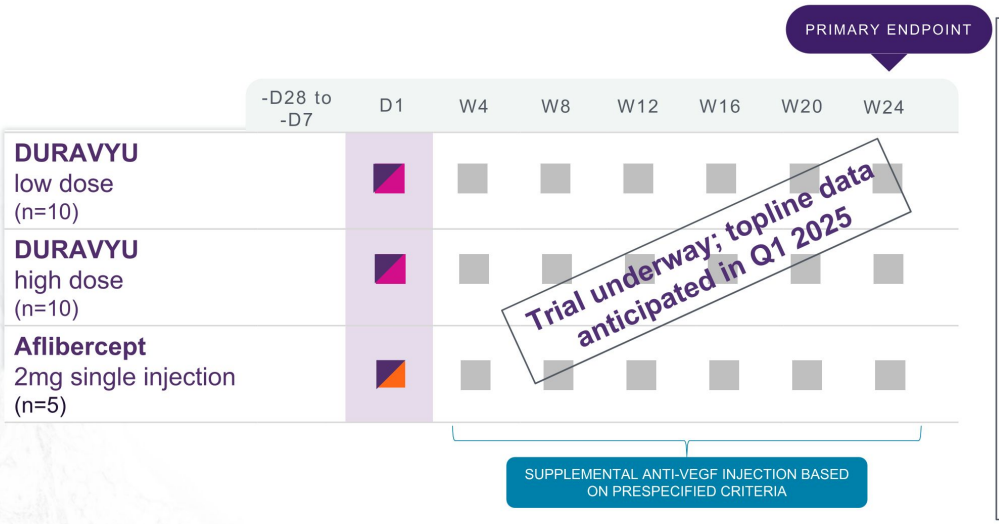
FDA, Food and Drug Administration; NDA, New Drug Application; OUS, outside the United States; EOP2, end of Phase 2

DURAVYU: vorolanib in Durasert E™

PHASE 2 VERONA CLINICAL TRIAL IN DIABETIC MACULAR EDEMA (DME)

EyePoint Pharmaceuticals

Phase 2 VERONA Clinical Trial is a Randomized, Open-Label, Aflibercept Controlled Trial with a Single DURAVYU Injection



- Potential 6-month treatment in previously treated DME patients
- Objectives:
  - Evaluate the safety and efficacy of two doses of DURAVYU in the DME patient population
  - Collect dose-ranging data to inform future clinical trials
- Primary endpoint: time to supplemental anti-VEGF injection up to week 24
- Secondary endpoints: Change in BCVA vs. aflibercept control, stable anatomical outcome as measured by OCT, DRSS over time

EYEPOINT PHARMACEUTICALS

VERONA Primary Endpoint: Time to Supplemental Injection up to Week 24 – Supplement Criteria

Starting at Week 4:

- Reduction in BCVA ≥10 letters due to DME[1]
- Reduction in BCVA of 5-9 letters **and** >75 microns of new fluid at two consecutive visits[1]
- Increase of ≥100 microns of new fluid vs. Baseline (Day 1)[2]
- Investigator discretion

Starting at Week 12:

- Lack of 10% reduction in CST compared to Baseline (Day 1)

1. vs. best on study measurement; 2. as measured by Spectral domain OCT (SD-OCT)
BCVA, best corrected visual acuity; CST, central subfield thickness

EyePoint PHARMACEUTICALS

EYP-2301: razuprotafib in Durasert E™

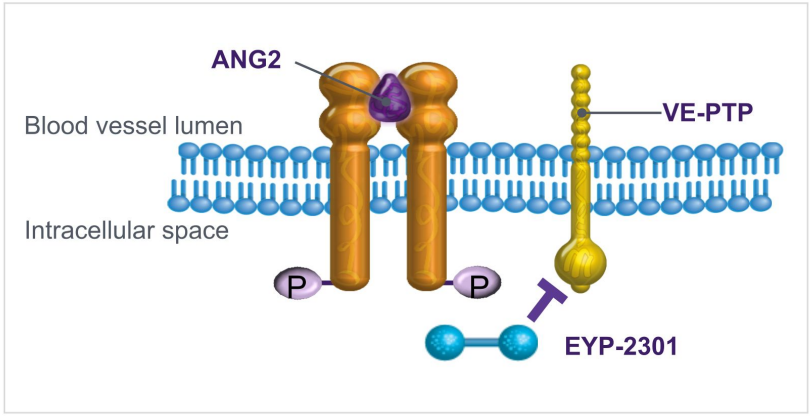
A SUSTAINED DELIVERY TIE-2 AGONIST FOR SEVERE RETINAL DISEASES

EyePoint Pharmaceuticals

EYP-2301: Razuprotafib in Durasert E™ is Being Developed as a Sustained Delivery Treatment for Serious Retinal Diseases

EYP-2301 targets vascular endothelial protein tyrosine phosphatase (VE-PTP) to promote TIE-2 activation and maintain vascular stability in the retina

- Tie-2 activation combined with VEGF inhibition has the potential to **enhance efficacy and extend durability**[1] of treatment
- In the retina, activated TIE-2 controls endothelial cell proliferation, barrier function and intercellular contacts, **stabilizing vessels and the blood-retinal barrier**[2]
- Razuprotafib (f/k/a AKB-9778) delivered subcutaneously was previously studied demonstrating preclinical and **clinical proof of concept** in posterior segment disease [3,4]



1. Heier et al. Retina, 2021;41:1-19. and Joussen et al. Eye 2021; 35:1305-1316.; 2. Hammes, et. Al – Diabetes.2011 Jan 1; 3. Shen et al. JCI, 2014; 124:4564; 4. Campochiaro et al. Ophthalmology, 2016; 123:1722-1730

EyePoint Pharmaceuticals

Cash runway through topline data in 2026 of pivotal Phase 3 clinical trials for DURAVYU in wet AMD

Strong Balance Sheet

- **$299M** of cash and investments on March 31, 2023
- No debt

Continued Execution And Well-Funded Through Key DURAVYU Milestones

DURAVYU™

✓	VERONA - DME Phase 2 Trial initiation	Q1 2024
✓	FDA conditional approval of DURAVYU proprietary name	March 2024
✓	EOP2 meeting with FDA for wet AMD	Q2 2024
✓	PAVIA topline data	Q2 2024
☐	**DAVIO 2 12-month data**	**Q2 2024**
☐	**PAVIA 12-month data**	**Q3 2024**
☐	**First wet AMD Phase 3 trial (LUGANO) initiation**	**2H 2024**
☐	**VERONA topline data**	**Q1 2025**

Corporate

✓	Appointed new Chief Medical Officer	March 2024
✓	Expanded SAB with world-renowned retina specialists	April 2024
☐	R&D Day	June 2024

*EOP2, End of Phase 2; wet AMD, wet age-related macular degeneration; SAB, Scientific Advisory Board

EyePoint PHARMACEUTICALS

Investor Presentation

May 2024