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): June 05, 2023

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)

480 Pleasant Street Watertown, Massachusetts

(Address of Principal Executive Offices)

000-51122 (Commission File Number) 26-2774444 (IRS Employer Identification No.)

> 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)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D 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:

	Trading	
Title of each class	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 \Box

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 June 5, 2023, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing it has completed enrollment in the Phase 2 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment for moderate to severe non-proliferative diabetic retinopathy (NPDR). The trial exceeded its original target of 60 patients, enrolling a total of 77 patients. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

On the same date, the Company posted an updated investor presentation on its website at www.eyepointpharma.com. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of EyePoint Pharmaceuticals, Inc. dated June 5, 2023
99.2	Investor Presentation of EyePoint Pharmaceuticals, Inc. dated June 5, 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: June 5, 2023

By: /s/ George O. Elston

George O. Elston Chief Financial Officer



EyePoint Pharmaceuticals Completes Enrollment in Phase 2 PAVIA Clinical Trial of EYP-1901 in Non-Proliferative Diabetic Retinopathy

Significant investigator and patient interest drove strong recruitment of 77 patients exceeding the 60 patient target –

Topline PAVIA data anticipated in 2Q 2024 –

WATERTOWN, Mass., June 5, 2023 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced it has completed enrollment in the Phase 2 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment for moderate to severe non-proliferative diabetic retinopathy (NPDR).

"We are delighted to report the completion of enrollment in the Phase 2 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment for NPDR," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "We are particularly pleased to have enrolled 77 patients in this trial, exceeding the 60 patient target, and look forward to reporting topline data in the second quarter of 2024. We are excited about the potential of EYP-1901 in NPDR. Despite the risk for visual loss associated with this disease, over 90% of patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. This is due to the burdensome and frequent eye injections currently required with today's approved therapies for this disease. As a result, we believe EYP-1901 may address the substantial therapeutic unmet need for a long-acting treatment."

PAVIA is a 12-month, randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with moderate to severe NPDR. The trial enrolled 77 patients randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg), or to the control group receiving a sham injection. EYP-1901 is delivered with a single intravitreal injection in the physician's office. The primary efficacy endpoint of the trial is improvement of at least two diabetic retinopathy severity scale (DRSS) levels as of week 36 after the EYP-1901 injection. Secondary endpoints include reduction in vision-threatening complications, occurrence of diabetic macular edema and/or proliferative disease, retinal ischemia/nonperfusion and safety. More information about the study is available at clinicaltrials.gov (identifier: NCT05383209).

"NPDR is a serious eye disorder affecting almost one-third of adults over the age of 40 with diabetes. It can lead to severe vision loss if left uncontrolled, however, the only approved treatments for this chronic disease are short-acting and require frequent office visits and intraocular injections. This leads to a passive treatment approach with no active drug therapy as the existing standard-of-care," said Jay S. Duker, M.D., President and Chief Operating Officer of EyePoint Pharmaceuticals. "There was a high-level of enthusiasm from practitioners, caregivers, and patients during the enrollment of the PAVIA trial, and, speaking from my experience as a practicing retina specialist, I am incredibly excited about the potential of treating NPDR patients with EYP-1901 every 9-months or longer to actively safeguard patients' vision between eye examinations. We thank the trial investigators, patients, and our internal team for completing trial enrollment swiftly and for their continued confidence in EYP-1901."

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment for retinal disease combining an erodible formulation of EyePoint's proprietary Durasert[®] delivery technology (Durasert ETM) with vorolanib, a tyrosine kinase inhibitor. Positive safety and efficacy data from the Phase 1 DAVIO clinical trial of EYP-1901 in wet AMD showed a positive safety profile with stable visual acuity and OCT. Further, the data demonstrated an impressive treatment burden reduction of 75% at six months and 73% at the 12-month visit following a single dose of EYP-1901. Phase 2 trials are fully enrolled in wet AMD and nonproliferative diabetic retinopathy, and a diabetic macular edema trial is planned for initiation in 1Q 2024. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

About Non-Proliferative Diabetic Retinopathy

Diabetic retinopathy affects approximately 40 percent of people with diabetes and is projected to impact 14.6 million Americans by 2050. Non-proliferative diabetic retinopathy (NPDR) is the early stage of the disease in which symptoms may be mild or nonexistent. In NPDR, the blood vessels in the retina are weakened, and tiny bulges in the blood vessels, called microaneurysms, may leak fluid into the retina. This leakage may lead to swelling of the macula and cause vision changes and blurriness. NPDR can lead to more serious complications or severe vision loss if left uncontrolled. The current standard of care for patients with moderate to severe NPDR includes intravitreal injections of anti-VEGF agents or laser photocoagulation, which can become a burden on patients, caregivers, and physicians due to the longevity of the disease and need for consistent therapies.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary erodible Durasert E^{TM} technology for sustained intraocular drug delivery including EYP-1901, an investigational sustained delivery intravitreal anti-VEGF treatment currently in Phase 2 clinical trials. The proven Durasert[®] drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. For more information visit <u>www.eyepointpharma.com.</u>

EYEPOINT SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the sufficiency of our existing cash resources into 2025; our plans and any other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments, including statements containing the words "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint's actual results to be materially different than those expressed in or implied by EyePoint's forward-looking statements. For EyePoint, this includes uncertainties regarding our ability to realize the anticipated benefits of the 2023 sale of YUTIQ® to Alimera Sciences including our potential to receive additional payments from Alimera pursuant to the our agreements with Alimera; our ability to manufacture YUTIQ in sufficient quantities pursuant to our commercial supply agreements with Alimera and Ocumension Therapeutics; 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; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the success of current and future license agreements, including our agreements with Alimera, Ocumension, Equinox Science and Betta 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 competition; market acceptance of our products, including our out-licensed products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; the impact of instability in general business and economic conditions, including changes in inflation, interest rates and the labor market; the extent to which COVID-19 impacts our business and the medical community; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; the sufficiency of the Company's cash resources and need for additional financing; 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.

Investors:

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Media Contact: Amy Phillips Green Room Communications

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Investor Presentation

June 2023

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 our potential to receive future payments from Alimera pursuant to our May 2023 sale and license agreement with Alimera; the sufficiency of our existing cash resources into 2025; our 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 dat; 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; 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 informate and the medical community, the impact of instability in general business and the Redica; the extent to which COVID-19 impacts and the results and the medical community the impact of instability in general business and Exchange Commission. We cannot guarantee that the results and the

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PHARMACEUTICALS

COMPANY OVERVIEW

Committed to developing therapeutics to improve the lives of patients with serious eye disorders

Pipeline represents multi billion-dollar product opportunities

- EYP-1901 sustained delivery intravitreal (IVT) insert of novel TKI vorolanib in retinal disease
 - Topline Phase 2 data in wet AMD anticipated in December 2023 and NPDR in 2Q 2024

Durasert® - proven IVT drug delivery technology

- Single in-office IVT injection
- Constant, sustained and stable release of drug
- Safely administered to ~80,000 patient eyes across four FDA approved products

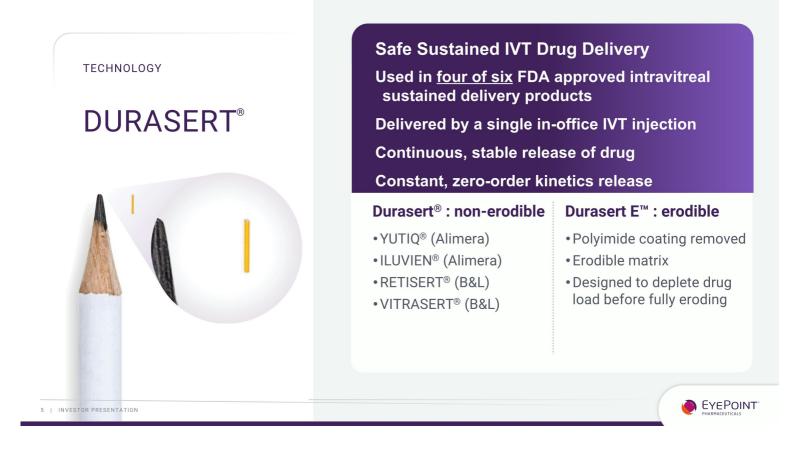
Strong Balance Sheet

- \$122M of cash and investments on March 31, 2023
- YUTIQ[®] sold in May 2023 for \$82.5M plus future royalties; \$75M upfront and \$7.5M payable in 2024
- All bank debt retired from YUTIQ upfront adding \$40M+, net
- Cash runway into 2025

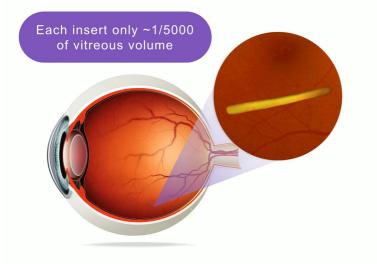
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Pipeline Represents Multibillion Dollar Product Opportunities

single dose	onth maintenance e 9-month treatme		•	Dec	pline data in cember 2023 ine data in Q2 2024
	e 9-month treatme	ent		Topl	
single dose 6-m	onth treatment			Trial	Initiation in Q1 2024
					ential product didate in 2024



EYP-1901 Delivers VEGF Receptor Binding Vorolanib Using Durasert E[™]



- •A single IVT injection of up to 3 inserts
- •New MOA in potential treatment of VEGF mediated retinal diseases
- Potentially complementary to approved anti-VEGF therapies
- •Sustained delivery of drug between ~6-9 months from single injection
- Positive safety and efficacy results in wet AMD from Phase 1 DAVIO clinical trial

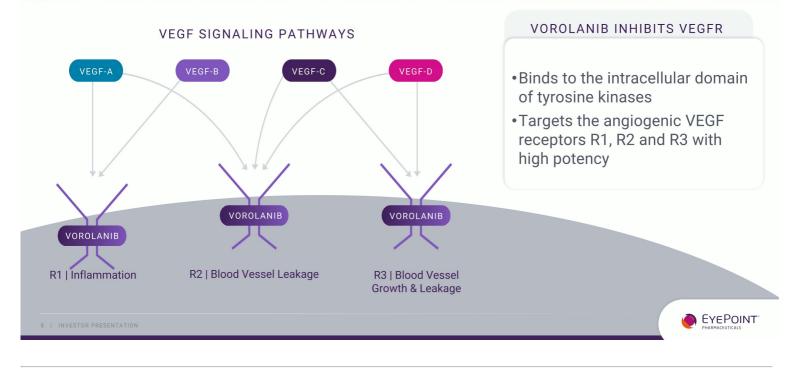
6 | INVESTOR PRESENTATION

Vorolanib is a selective tyrosine kinase inhibitor

- Composition of matter patent into 2037
- Previous Phase 1 and Phase 2 clinical trials in wet AMD as an oral therapy showed compelling safety and efficacy data with <u>no ocular toxicity observed</u>^{1,2}
- In-vivo studies demonstrate encouraging neuroprotection data and potential antifibrosis effect³
- Reduced off-target binding of receptors associated with TKI systemic side effects

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Vorolanib Binds Receptors Of All VEGF Growth Factors With Strong Affinity To VEGF Receptor 2 - A Receptor Associated With Blood Vessel Leakage



EYP-1901

PHASE 1 DAVIO CLINICAL TRIAL RESULTS

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FAVORABLE SAFETY PROFILE

- No ocular SAEs reported
- No drug-related systemic SAEs reported
- Ocular AEs majority are mild and expected

POSITIVE EFFICACY & DURABILITY

- Stabilization of mean BCVA and OCT throughout 6 months was achieved
- 53% supplemental anti-VEGF supplement injection free up to 6-months
- 75% reduction in treatment burden at 6months

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SIX MONTHS MEDIAN TIME TO SUPPLEMENTAL ANTI-VEGF INJECTION



EYP-1901

Phase 1 DAVIO clinical trial demonstrated a favorable safety profile, meeting the primary safety endpoint

Favorable safety profile

- No ocular serious adverse events (SAEs)
- No drug related systemic SAEs
- No drug related ocular or systemic toxicity
- No Durasert related toxicity or tolerance issues
- No dose limiting toxicity

No ocular AEs of key interest observed

• NO vitreous floaters, endophthalmitis, retinal detachment, implant migration in the anterior chamber, retinal vasculitis, posterior segment inflammation

Ocular AEs observed:

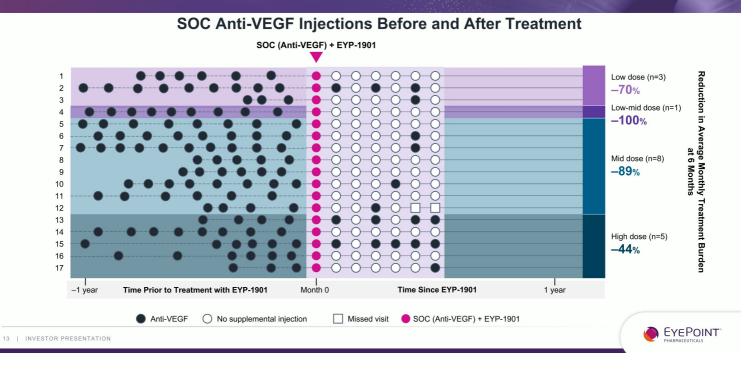
- One eye: mild asymptomatic anterior chamber cell/flare
- One eye: asymptomatic vitreous hemorrhage from injection observed

BCVA and CST Stable At 6 And 12 Months After Single Treatment Of EYP-1901 In The DAVIO Clinical Trial

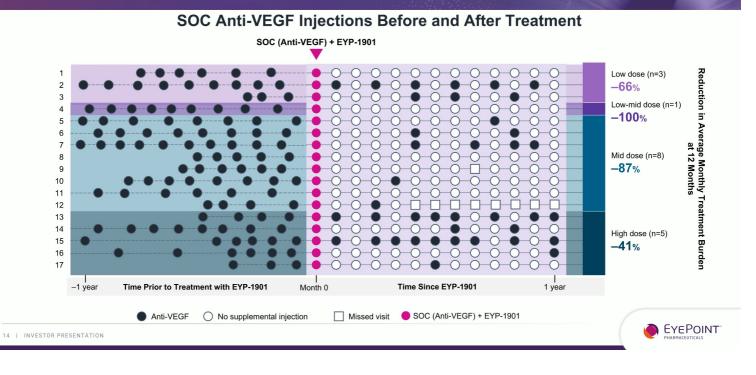
	Parameter	6 Months	12 Months	
1	BCVA	-2.5	-4.1]
1	CST	-3.4	-2.8	
	pos.		200 100 0 • • • • • • • • • • • • • • • • • • •	
BCVA: best corrected visual acuity	OCT: optical coher CST: central subfie			
TOR PRESENTATION		Error bars represent the st	andard deviation.	

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EYP-1901 Phase 1 DAVIO Clinical Trial Demonstrated Clinically Significant Reduction In Treatment Burden Of 75% At 6-Months

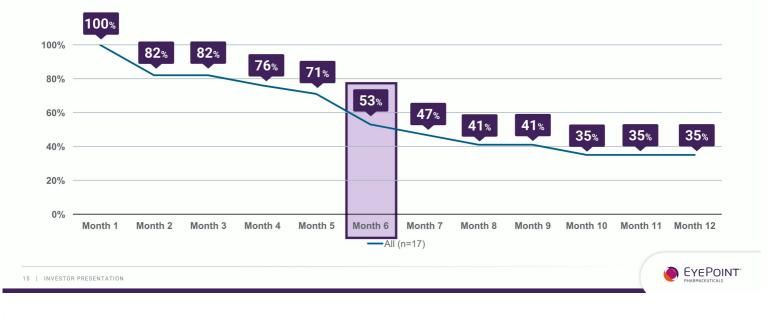


EYP-1901 Phase 1 DAVIO Clinical Trial Maintained A Clinically Significant Reduction In Treatment Burden Of 73% At 12-Months



EYP-1901 Phase 1 DAVIO Clinical Trial Demonstrated That 53% Of Patients Did Not Require Supplemental Anti-VEGF Treatment At 6-Months

Median time to supplemental anti-VEGF: 6 months



EYP-1901

PHASE 1 DAVIO CLINICAL TRIAL SUBGROUP ANALYSIS – NINE SUBJECTS WITH NO EXCESS FLUID AT SCREENING

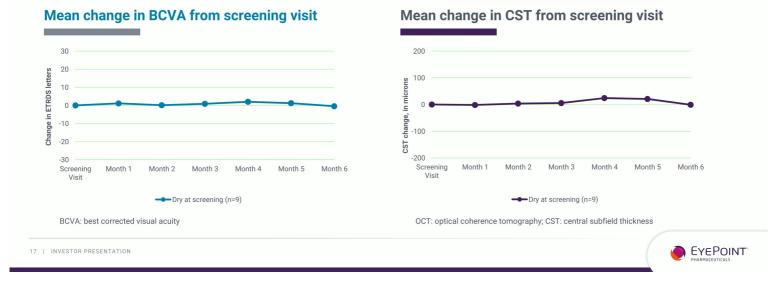
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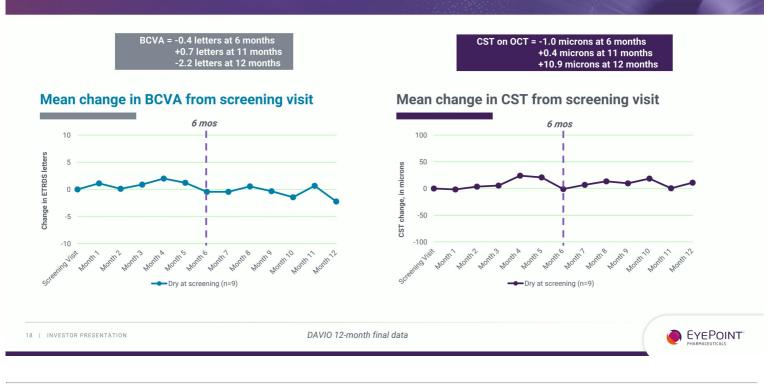
DAVIO Subgroup With No Excess Fluid At Screening Showed Stable BCVA and CST At 6-Months

BCVA = -0.4 letters at 6 months

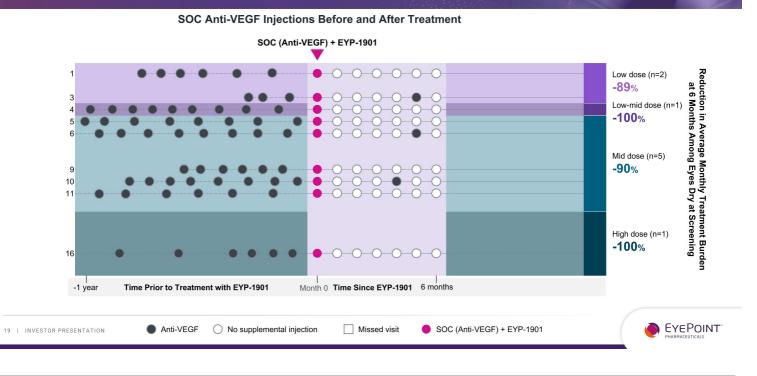
CST on OCT = -1.0 microns at 6 months



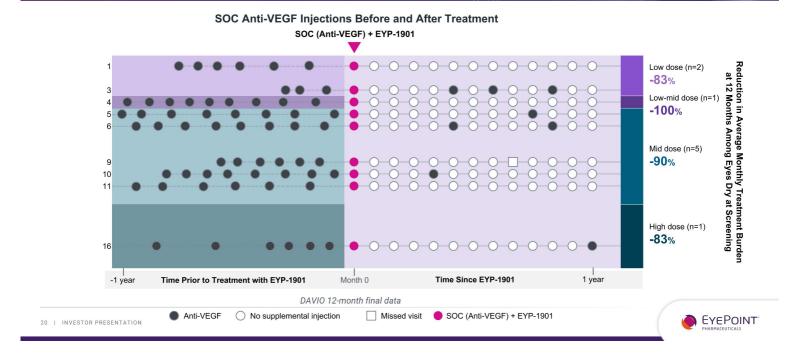
DAVIO Subgroup With No Excess Fluid At Screening Showed Stable BCVA and CST Through 12-Months



DAVIO Subgroup With No Excess Fluid At Screening Showed A 92% Reduction In Treatment Burden At 6 Months



DAVIO Subgroup With No Excess Fluid At Screening Showed An 89% Reduction In Treatment Burden At 12-Months

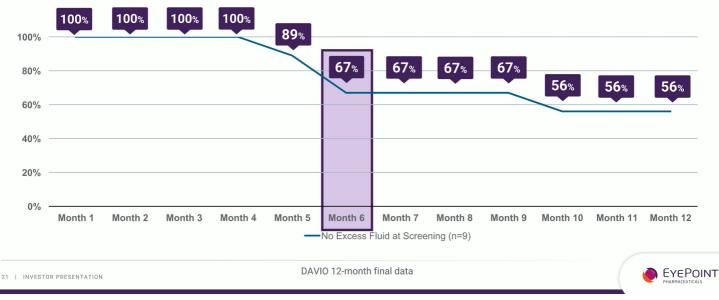


DAVIO Subgroup With No Excess fluid At Screening Demonstrated That 67% Did Not Require A Supplemental Anti-VEGF Injection At 6-Months

100% 100% 100% 100% **89**% 100% 67% 67% 67% 67% 80% 60% 40%

Median time to supplemental anti-VEGF: 12 months

20%

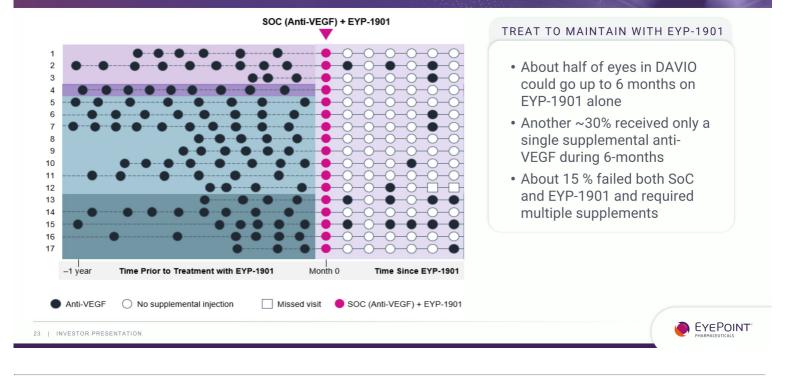


EYP-1901

TREAT TO MAINTAIN IN WET AMD

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DAVIO Clinical Trial Data Supports Advancing EYP-1901 As A Maintenance Treatment For Wet AMD



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

- Treat newly diagnosed patients with anti-VEGF of choice to reach desired "dry" outcome
- *Maintain* with EYP-1901on six-month intervals providing new MOA and sustained delivery
- Supplement with current anti-VEGF biologic, if needed

Based on DAVIO Phase 1 outcomes, we believe <u>over half</u> of all wet AMD eyes may be maintained visually and anatomically with EYP-1901 alone

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EYP-1901

WET AMD PHASE 2 CLINICAL TRIAL - DAVIO 2

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DAVIO 2 CLINICAL TRIAL

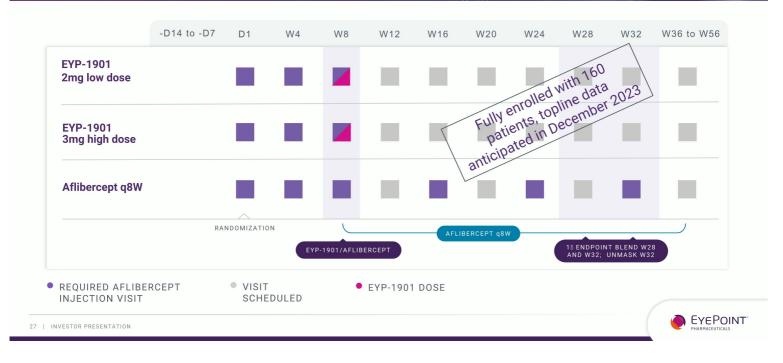
The Phase 2 DAVIO 2 clinical trial for EYP-1901 in wet AMD was designed to support initiation of Phase 3 clinical trials in 2024

Phase 2 design includes DAVIO Phase 1 learnings and FDA interaction

- Type C meetings held with FDA
- CST below 350um at screening to eliminate poor responders to standard of care treatment
- Only previously treated wet AMD patients
- Primary outcome is difference in change in BCVA at Week 28 and 32 (blended)

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



EYP-1901

NON-PROLIFERATIVE DIABETIC RETINOPATHY - PHASE 2 CLINICAL TRIAL (PAVIA)

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Diabetic Retinopathy Market Opportunity

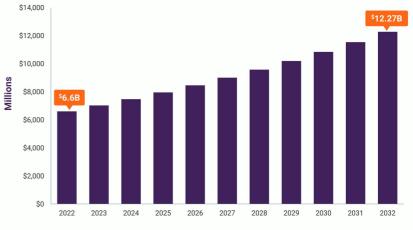
- Leading cause of blindness
- Current SoC is watchful waiting until vision loss

ewResearch.com), Global Diabetic Re an. 2022 (MarketDataForecast.com)

 Significant opportunity for a 9-month sustained delivery treatment with EYP-1901

> .020 popathy Market Size

Growing Global DR Market



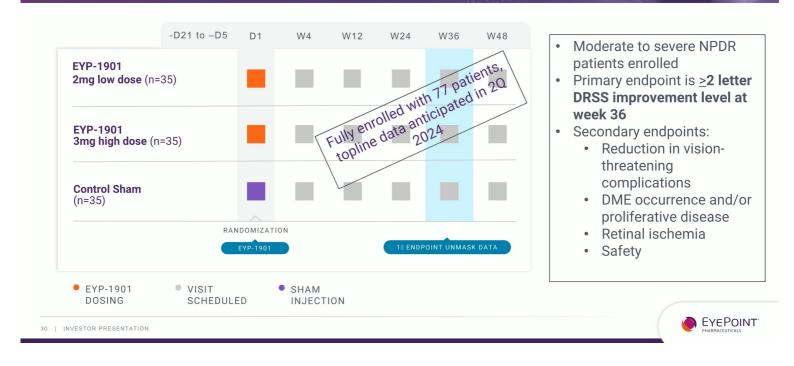
Analysis includes North America, Europe, Asia Pacific, Latin America, Middle East, and Africa

\$12.27 billion

is the estimated market size by 2032, a result of diabetes prevalence and the aging population



EYP-1901 Phase 2 PAVIA Clinical Trial Is Randomized Double-Masked, Single Injection With Sham Control As A 9-Month Treatment In NPDR



Solid cash position and cash runway into 2025 while funding Phase 2 trials for EYP-1901

Strong Balance Sheet

- \$122M of cash and investments on March 31, 2023
- YUTIQ[®] sold for \$82.5M plus future royalties in May 2023; \$75M upfront and \$7.5M payable in 2024
- <u>All</u> bank debt retired from YUTIQ upfront adding \$40M+ to balance sheet

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• Cash runway into 2025

Continued Execution And Well Funded Through Key EYP-1901 Milestones

	EYP-1901	
1	DAVIO 1 trial complete	2Q 2022
1	DAVIO 2 trial initiated	3Q 2022
1	PAVIA trial initiated	3Q 2022
1	DAVIO 2 enrollment complete	1Q 2023
1	PAVIA enrollment complete	2Q 2023
	DAVIO 2 topline data	December 2023
	DME Trial initiation	1Q 2024
	PAVIA topline data	2Q 2024
	Corporate	
1	RallyBio complement inhibitor (C5) collaboration	1Q 2023
1	YUTIQ transacted for \$82.5M plus royalties	2Q 2023
1	Debt retired and cash runway extended into 2025	2Q 2023
IVESTOR PRESE	NTATION	



