

**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): September 11, 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 September 11, 2023, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing positive interim masked safety data for its lead product candidate EYP-1901 from the Company's ongoing Phase 2 PAVIA trial evaluating EYP-1901 as a potential nine-month treatment for moderately-severe to severe non-proliferative diabetic retinopathy (NPDR) and DAVIO 2 trial as a potential six-month sustained delivery maintenance treatment for wet age-related macular degeneration (wet AMD).

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of EyePoint Pharmaceuticals, Inc. dated September 11, 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: September 11, 2023

By: /s/ George O. Elston
George O. Elston
Chief Financial Officer

EyePoint Pharmaceuticals Reports Positive Masked Safety Update for Lead Product Candidate EYP-1901 in Ongoing PAVIA and DAVIO 2 Phase 2 Clinical Trials as of September 1, 2023

- *Interim analysis of masked data shows EYP-1901 is well tolerated with no reported drug-related ocular or systemic serious adverse events in Phase 2 PAVIA clinical trial in non-proliferative diabetic retinopathy -*
- *Updated interim analysis of masked safety data of Phase 2 DAVIO 2 trial in wet AMD continues to show a positive safety profile with no reported drug-related ocular or systemic SAEs -*
- *Company remains on-track to report topline data for Phase 2 DAVIO 2 trial in December 2023 and Phase 2 PAVIA trial in 2Q 2024 -*

WATERTOWN, Mass., September 11, 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 positive interim masked safety data for its lead product candidate EYP-1901 from the Company’s ongoing Phase 2 PAVIA trial evaluating EYP-1901 as a potential nine-month treatment for moderately-severe to severe non-proliferative diabetic retinopathy (NPDR) and DAVIO 2 trial as a potential six-month sustained delivery maintenance treatment for wet age-related macular degeneration (wet AMD). All treatment arms in the PAVIA trial have reached at least 3-months post-dosing follow-up as of September 1, 2023.

Approximately 170 patients have received EYP-1901 with a minimum of three months of follow-up post injection from the ongoing Phase 2 PAVIA and DAVIO 2 clinical trials and the completed DAVIO 1 trial with no reported drug-related ocular severe adverse events (SAEs) and no reported drug-related systemic SAEs.

“We remain very encouraged by the positive masked safety results that EYP-1901 has produced to-date in the 17 patients dosed in the Phase 1 DAVIO trial in wet AMD as well as approximately 150 additional patients in our two Phase 2 clinical trials: DAVIO 2 and PAVIA. These results bolster our confidence in EYP-1901 as a potentially paradigm-shifting treatment for patients who would benefit from a safe, sustained therapeutic option for VEGF-mediated diseases,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. “In the 77 patients enrolled in the Phase 2 PAVIA trial, the investigators report no drug-related ocular SAEs and no drug-related systemic SAEs, demonstrating EYP-1901’s excellent safety profile in NPDR for the first time. We remain excited about the potential for EYP-1901 in NPDR, a chronic disease where over 90% of patients currently receive no course of treatment apart from observation by their eye care specialist until they develop sight-threatening complications. We remain on-track to share our topline results from the DAVIO 2 trial in December of this year and from the PAVIA trial in the second quarter of 2024.”

In the PAVIA clinical trial, there have been no reported drug-related ocular SAEs and no reported drug-related systemic SAEs. There were two ocular SAEs deemed unrelated to EYP-1901 by investigators:

- Hemorrhagic posterior vitreous detachment (PVD) in a study eye eight weeks after dosing
 - Macular edema leading to vision loss in the non-study fellow eye
-

PAVIA is a 12-month, randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with moderately-severe 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, similar to current FDA approved anti-VEGF treatments. 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).

DAVIO 2 is a randomized, controlled Phase 2 clinical trial of EYP-1901 in patients with previously treated wet AMD. All enrolled patients had been previously treated with standard-of-care anti-VEGF therapy and were randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg) or an aflibercept control. EYP-1901 is delivered with a single intravitreal injection in the physician's office, similar to current FDA approved anti-VEGF treatments. The primary efficacy endpoint of the DAVIO 2 trial is change in BCVA compared to the aflibercept control, six-months after the EYP-1901 injection. Secondary efficacy endpoints include change in CST as measured by optical coherence tomography (OCT), number of eyes that remain free of supplemental anti-VEGF injections, number of aflibercept injections in each group, and safety. More information about the trial is available at clinicaltrials.gov (identifier: NCT05381948).

About EYP-1901

EYP-1901 is being developed as an investigational sustained delivery treatment for retinal disease combining a bioerodible formulation of EyePoint's proprietary Durasert® delivery technology (Durasert E™) 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 non-proliferative diabetic retinopathy, and a diabetic macular edema trial is planned for initiation in Q1 2024. Vorolanib is licensed to EyePoint exclusively by Equinox Sciences for the localized treatment of all ophthalmic diseases.

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™ 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 www.eyepointpharma.com.

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 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; 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 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. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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