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): December 04, 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 December 4, 2024, EyePoint Pharmaceuticals, Inc. issued a press release announcing the first patient dosed in the Phase 3 LUCIA clinical trial of DURAVYU™, formerly EYP-1901, for the treatment of 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.

Exhibit No.	Description
99.1	Press Release of EyePoint Pharmaceuticals, Inc. dated December 4, 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: December 4, 2024

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

Exhibit 99.1

EyePoint Announces First Patient Dosed in Second Global Phase 3 LUCIA Clinical Trial of DURAVYU™ for the Treatment of Wet Age-Related Macular Degeneration

– Topline data for Phase 3 pivotal program anticipated in 2026 –

WATERTOWN, Mass., December 4, 2024 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases, today announced that the first patient has been dosed in the LUCIA trial, the Company's second global Phase 3 clinical trial of DURAVYU, formerly EYP-1901, for the treatment of wet age-related macular degeneration (wet AMD). DURAVYU is an investigational sustained delivery therapy delivering patent-protected vorolanib, a selective tyrosine kinase inhibitor formulated in proprietary bioerodible Durasert E™ for sustained intraocular delivery.

"Dosing the first patient in our second global Phase 3 clinical trial, the LUCIA trial, marks another significant milestone demonstrating our continued focus on execution at EyePoint," said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. "We are encouraged by the robust physician and patient interest in DURAVYU with enrollment in our first pivotal trial, the LUGANO trial, exceeding our expectations. With two simultaneous Phase 3 clinical trials underway, the most robust clinical dataset of all long-acting treatments in development for wet AMD, and a strong balance sheet, we are well-positioned as the leader in sustained-release ocular drug delivery bringing impactful therapies to patients suffering from serious retinal diseases."

"We are pleased to have dosed the first patient in the LUCIA trial so soon after dosing the first patient in the LUGANO trial. This underscores our commitment to develop innovative therapies with the potential to change the current treatment paradigm in wet AMD," said Ramiro Ribeiro, M.D., Ph.D., Chief Medical Officer of EyePoint. "The Phase 3 pivotal program is the first and only sustained release wet AMD pivotal program evaluating re-dosing in both trials. Following a typical non-inferiority approval pathway, the LUGANO and LUCIA trials will provide data on the efficacy, durability, safety and dosing flexibility of treatment with DURAVYU and have the potential to provide the retina community valuable insights on how DURAVYU could be used in 'real-world' practice. With over 240 global sites already committed across both Phase 3 trials and exceptional patient and investigator enthusiasm, we are confident we can rapidly enroll patients in the Phase 3 pivotal trials."

"Patients with wet AMD typically require life-long treatment with frequent intravitreal injections to preserve their vision. This high treatment burden often results in under-treatment and irreversible vision loss," said Adam Gerstenblith, M.D., principal investigator in the LUCIA clinical trial and vitreoretinal surgeon at Mid Atlantic Retina Specialists. "The Phase 3 LUCIA trial is an important step forward in our pursuit of more durable treatments that are safe and effective. Moreover, the design of the LUCIA trial includes both treatment naïve and previously treated wet AMD patients, as well as re-dosing of DURAVYU every six months, which aligns well with how we would approach potential treatment using DURAVYU in clinical practice. We are proud to be the site to treat a patient with DURAVYU in the LUCIA trial and we look forward to continuing to work with EyePoint to rapidly enroll patients in this critical Phase 3 program."

LUGANO and LUCIA are global, randomized, double-masked, aflibercept controlled, non-inferiority Phase 3 trials assessing the efficacy and safety of DURAVYU in patients with active wet AMD including treatment naïve and treatment experienced patients. Each trial is expected to enroll approximately 400 patients globally who will be randomly assigned to a 2.7mg dose of DURAVYU or an on-label

aflibercept control. The LUGANO and LUCIA trials are the only sustained release wet AMD pivotal Phase 3 trials evaluating re-dosing in both trials. Patients in the DURAVYU treatment arm will receive an intravitreal injection of DURAVYU every six months, starting at month two of the trial. DURAVYU is delivered via a standard intravitreal injection in the physician's office, similar to current standard practice with FDA approved anti-VEGF treatments. The primary endpoint of the Phase 3 pivotal trials is the average change in best corrected visual acuity (BCVA) at weeks 52 and 56 versus baseline. Secondary endpoints include safety, reduction in treatment burden, percentage of eyes free of supplemental aflibercept injections and anatomical results as measured by optical coherence tomography (OCT). More information about the trial is available at clinicaltrials.gov (LUGANO identifier: NCT06668064; LUCIA identifier: NCT06683742).

About Wet AMD

Wet age-related macular degeneration (wet AMD) is a leading cause of vision loss and irreversible blindness in people over the age of 50. Wet AMD is an advanced form of condition that develops when abnormal blood vessels grow into the macular retina, leaking blood or fluid, and leading to potentially severe vision loss. Wet AMD is a lifelong disease that requires continuous treatment so that patients may maintain visual function. Although multiple treatments are now available, challenges still exist as the current standard-of-care is dosed on average every two months in the United States under a treat-and-extend protocol, and these large molecule anti-VEGF treatments only target one pathology of the disease. This lifetime of frequent treatment represents a tremendous burden for patients, physicians, and the health care system, potentially leading to patient noncompliance and further vision loss.

About DURAVYU™

DURAVYU™, f/k/a EYP-1901, is being developed as a potential paradigm-altering treatment for patients suffering from VEGF-mediated retinal diseases. DURAVYU delivers vorolanib, a potent, selective and patent-protected tyrosine kinase inhibitor (TKI) as a solid bioerodible insert using EyePoint’s proprietary sustained-release Durasert E™ technology. Vorolanib brings a new mechanistic approach to the treatment of VEGF-mediated retinal diseases as a pan-VEGF receptor inhibitor, inhibiting all VEGF receptors. Further, in an in-vivo model of retinal detachment, vorolanib demonstrated neuroprotection and may have antifibrotic benefits as it also blocks PDGF. DURAVYU is shipped and stored at ambient temperature and is administered with a standard intravitreal injection in the physician's office. DURAVYU is immediately bioavailable with zero-order kinetics release for at least six months.

Positive data from both the Phase 1 DAVIO and Phase 2 DAVIO 2 clinical trials of DURAVYU in wet AMD demonstrated clinically meaningful efficacy data with stable visual acuity and CST and a favorable safety profile. Further, data from DAVIO 2 demonstrated an impressive treatment burden reduction of approximately 88% at eight months, six months after treatment with DURAVYU, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection through up to eight months, six months after treatment with DURAVYU. The data from the DAVIO 2 clinical trial supported the advancement of the wet AMD program and the initiation of the global Phase 3 clinical trials, LUGANO and LUCIA.

DURAVYU is also currently being studied in the Phase 2 VERONA trial for diabetic macular edema (DME). Full topline data is expected in the first quarter of 2025.

About EyePoint Pharmaceuticals

EyePoint (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology for

sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU™ (f/k/a EYP-1901), is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with bioerodible Durasert E™. DURAVYU is presently in Phase 3 global, pivotal clinical trials as a sustained delivery treatment for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States, and in a Phase 2 clinical trial in diabetic macular edema (DME). EyePoint expects full topline data from the Phase 2 clinical trial in DME in Q1 2025 and topline data from both Phase 3 pivotal trials in wet AMD in 2026.

Pipeline programs include EYP-2301, a TIE-2 agonist, razuprotafib, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases. The proven Durasert® drug delivery technology has been safely administered to thousands of patient eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

Vorolanib is licensed to EyePoint exclusively by Equinox Sciences, a Betta Pharmaceuticals affiliate, for the localized treatment of all ophthalmic diseases outside of China, Macao, Hong Kong and Taiwan.

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.

Forward Looking Statements

EYEPOINT PHARMACEUTICALS 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 our expectations regarding the timing and clinical development and potential of DURAVYU in wet AMD and DME, including our expectations regarding the pace of enrollment for the LUGANO trial and the LUCIA trial for wet AMD, and our beliefs and expectations regarding the anticipated announcement of full topline data from the VERONA trial in the first quarter of 2025; the belief that the interim results from the VERONA trial support DURAVYU's potential to advance to non-inferiority pivotal trials in DME; our beliefs and expectations regarding the anticipated full results from the VERONA trial; the potential for DURAVYU 2.7mg to extend treatment intervals while improving vision; the potential for DURAVYU to provide an immediate benefit over aflibercept control in both BCVA and CST; our optimism that that DURAVYU has the potential to shift the treatment paradigm in wet AMD and DME and improve patient outcomes; our expectations regarding clinical development of our other product candidates, including EYP-2301; our business strategies and objectives; and other statements identified by words such as "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, these risks and uncertainties include the timing, progress and results of the company's clinical development activities; uncertainties and delays relating to the design, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; the company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the risk that results of clinical trials may not be predictive of future results, and interim and preliminary data are subject to further analysis and may change as more data becomes available; unexpected safety or efficacy data observed during clinical trials; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for approval of the

company's product candidates; changes in the regulatory environment; changes in expected or existing competition; the success of current and future license agreements; our dependence on contract research organizations, and other outside vendors and service providers; product liability; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; delays, interruptions or failures in the manufacture and supply of our product candidates; the availability of and the need for additional financing; the company's ability to obtain additional funding to support its clinical development programs; uncertainties regarding the timing and results of the August 2022 subpoena from the U.S. Attorney's Office for the District of Massachusetts; uncertainties regarding the FDA warning letter pertaining to the company's Watertown, MA manufacturing facility; 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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