EyePoint Reports Corporate Update and Anticipated Pivotal Milestones for 2026

Jan 7, 2026

– Phase 3 programs underway for DURAVYU in wet AMD and DME, the largest multi-billion-dollar retinal disease markets –

– Pivotal Phase 3 trials in wet AMD on track for data readout beginning in mid-2026 –

– Phase 3 DME program first patient dosing expected in Q1 2026 –

– Presenting at the 44th Annual J.P. Morgan Healthcare Conference in San Francisco on Tuesday, January 13, 2026 at 7:30 a.m. PT –

WATERTOWN, Mass., Jan. 07, 2026 (GLOBE NEWSWIRE) -- EyePoint, Inc. (Nasdaq: EYPT), a company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases, today reported a corporate update and anticipated 2026 pivotal milestones for its lead product candidate, DURAVYU ™ (vorolanib intravitreal insert).

“Following an incredibly successful year of execution in 2025, EyePoint is positioned to deliver on key priorities across both of our late-stage programs, wet AMD and DME, in 2026,” said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. “As we prepare for a milestone-rich year, we continue to be guided by scientific rigor, a de-risked clinical approach, and a patient-centric focus that define our principles. With topline data from our Phase 3 wet AMD program anticipated beginning in mid-2026, we are actively preparing for an expeditious NDA filing and FDA review to ensure we deliver DURAVYU to patients as soon as possible. Additionally, we remain on track to dose the first patient in our Phase 3 DME program in the first quarter of 2026, further solidifying DURAVYU’s position as the only sustained release TKI in development for this multi-billion-dollar indication for which there is a significant need for new therapeutic options.”

Dr. Duker continued, “DURAVYU is uniquely poised to potentially disrupt the largest retinal disease markets, with a unique multi-mechanism of action, and a compelling profile within the retinal disease community. We remain focused on advancing DURAVYU as a best-in-class and first-in-class sustained delivery therapy to improve the lives of patients with serious retinal diseases.”

A Leader in Sustained Ocular Drug Delivery:

DURAVYU in Wet Age-Related Macular Degeneration (Wet AMD)

- Completed enrollment of over 900 patients across the Phase 3 LUGANO and LUCIA trials in 7 months, respectively, representing one of the fastest enrolling wet AMD pivotal programs, potentially positioning DURAVYU as first to market among all current investigational sustained delivery programs.
    - LUGANO randomized 432 patients in the U.S. with topline data anticipated in mid-2026.
    - LUCIA randomized 475 patients across U.S. and ex-U.S. sites with topline data to closely follow LUGANO.
    - LUGANO and LUCIA are identical, double-masked noninferiority trials, with an on-label aflibercept control, developed in alignment with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).
    - The Phase 3 wet AMD program has a primary endpoint of noninferiority in the change from baseline in best corrected visual acuity (BCVA) at weeks 52 and 56, blended, versus aflibercept on-label control with secondary endpoints including safety, superiority in reduction in treatment burden vs. on-label aflibercept, percentage of supplement-free eyes, and anatomical results. The Phase 3 data, if positive, are expected to support a compelling and clinically relevant label.
- Announced interim masked safety data through September 29, 2025, noting that the safety profile observed in LUGANO and LUCIA remains consistent with previous DURAVYU clinical trials.
    - The independent Data Safety Monitoring Committee (DSMC) completed its second scheduled review of the Phase 3 program and recommended continuation of the program as planned, with no protocol modifications.
- DURAVYU registration batches continue at EyePoint’s commercial manufacturing facility in Northbridge, Massachusetts to support the critical chemistry, manufacturing, and controls (CMC) section of a planned NDA filing.

DURAVYU in Diabetic Macular Edema (DME)

- Aligned with the FDA and EMA on the pivotal DME program following the established noninferiority pathway for potential approval.

- First patient dosing in both trials, COMO and CAPRI, is expected in Q1 2026. The identical trials will each enroll approximately 240 patients.
- Patients will be randomized on Day 1 to the DURAVYU 2.7mg arm (redosing every six months) or the on-label 2mg aflibercept control arm. The primary endpoint is the noninferiority change from baseline in BCVA at weeks 52 and 56, blended, versus aflibercept on-label control.

DURAVYU Data Presentations

- DURAVYU's multi-mechanism of action, including inhibition of IL-6 mediated inflammation and VEGF-mediated vascular permeability, was presented during Eyecelerator at the American Academy of Ophthalmology Annual Meeting in October 2025, demonstrating:
    - A greater than 50% reduction in IL-6 activity associated with DURAVYU via inhibition of JAK1 in an in-vitro model. IL-6 mediated inflammation and VEGF-mediated vascular permeability are both key contributors to wet AMD and DME.
    - The positive efficacy results from the Phase 2 VERONA trial, where a single DURAVYU 2.7mg dose demonstrated meaningful early and sustained improvements in vision and anatomy compared to aflibercept 2mg, which further underscores the potential clinical utility in DME.
- Accepted to present a clinical trial update for DURAVYU for retinal exudative diseases at the Hawaiian Eye and Retina 2026 conference, emphasizing the broad treatment potential of DURAVYU and enthusiasm from the retinal community for new treatment options in multiple serious retinal diseases.

Corporate Updates

- Completed an underwritten public offering with gross proceeds of $172.5 million in October 2025.
- Approximately $300 million[1] of cash and investments at December 31, 2025 with cash runway into the fourth quarter of 2027 beyond key milestones for the Phase 3 wet AMD program in 2026 and fully funding the Phase 3 pivotal DME program.
- Presenting at the 44th Annual J.P. Morgan Healthcare Conference in San Francisco on Tuesday, January 13, 2026 at 7:30 a.m. PT/10:30 a.m. ET. A webcast and subsequent archived replay of the presentation may be accessed via the Investors section of the Company website at www.eyepoint.bio.

[1]Unaudited estimate as of December 31, 2025.

About DURAVYU ™

DURAVYU ™ (vorolanib intravitreal insert), is an investigational sustained-delivery treatment for patients suffering from serious retinal diseases. DURAVYU is a solid bioerodible insert designed to release a therapeutic dose of vorolanib for at least six months and is administered via a routine in-office intravitreal injection with a sterile, prefilled syringe injector. DURAVYU combines vorolanib in next-generation Durasert E ™ technology. Durasert E is a proprietary and best-in-class bioerodible matrix designed to provide sustained release of drug without free-floating drug particles.

Vorolanib is a differentiated and patent-protected tyrosine kinase inhibitor (TKI) and is the most studied TKI in retinal disease, with no ocular safety signals noted in four prior trials. Vorolanib features a novel multi-mechanism of action as it targets both VEGF-mediated vascular permeability and IL-6 mediated inflammation through inhibition of all VEGF receptors and pro-inflammatory IL-6/JAK1 signaling. Vorolanib demonstrated neuroprotection in an in vivo model of retinal detachment and inhibits PDGF, which may provide antifibrotic effect.

DURAVYU has safety and efficacy data across approximately 140 wet AMD and DME patients from both Phase 1 and 2 trials that demonstrate stability in vision and anatomical control. Data from the DAVIO 2 Phase 2 trial in wet AMD demonstrated an impressive 88% reduction in treatment burden six months after treatment with DURAVYU, with over 80% of patients supplement-free or receiving only one supplemental anti-VEGF injection. No safety signals observed in 190+ patients across four completed clinical trials, including three Phase 2 trials.

The wet AMD Phase 3 pivotal program (LUGANO and LUCIA) is the only investigational program evaluating every six-month dosing of DURAVYU, potentially providing a flexible label for physicians. The Phase 3 pivotal program follows a well-established regulatory approval pathway with a patient-centric noninferiority design comparing DURAVYU to on-label standard of care to inform real-word treatment practices.

DURAVYU is also being advanced for the treatment of DME with first patient dosing in Phase 3 trials (COMO and CAPRI) expected in the first quarter of 2026. The Phase 2 VERONA trial in DME met primary and secondary endpoints and demonstrated a rapid and sustained improvement in vision and anatomy, and a continued favorable safety and tolerability profile with superior dosing intervals to standard of care.

About EyePoint

EyePoint, Inc. (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases. The Company's lead product candidate, DURAVYU ™, is an innovative investigational sustained delivery treatment for serious retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor, in next-generation bioerodible Durasert E ™ technology. Supported by robust safety and efficacy data across multiple clinical trials and indications, DURAVYU is currently being evaluated in Phase 3 pivotal trials for wet age-related macular degeneration with expected topline data beginning in mid-2026. First patient dosing in the pivotal Phase 3 clinical trials in diabetic macular edema is expected in the first quarter of 2026.

The Company is committed to partnering with the retina community to improve patient lives while creating long-term value, with four approved drugs over three decades and tens of thousands of eyes treated with EyePoint innovation.

EyePoint is headquartered in Watertown, Massachusetts, with a commercial manufacturing facility in Northbridge, 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 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 our clinical development and regulatory plans; our belief that DURAVYU ™ is well-positioned to be the first-to-market among all investigational sustained release treatments for wet AMD; our belief that DURAVYU is the only TKI in development for DME; our belief that DURAVYU is uniquely positioned to potentially address both VEGF-mediated vascular leakage and IL-6 mediated inflammatory drivers of DME as a sustained delivery therapy; our belief that DURAVYU's potential real-world application in multiple retinal disease indications and established trial designs position DURAVYU for clinical and commercial success; our expectations regarding timing for commencement of DME clinical trial enrollment and the timing of the availability and release of wet AMD clinical data; our expected cash runway; our belief that DURAVYU has the potential to maintain a majority of patients with active disease with no supplemental anti-VEGF therapy for six months or longer; and our expectations regarding the timing and clinical development of our other product candidates, including EYP-2301; and other statements regarding the Company's future plans, objectives, strategies and beliefs, as identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," or 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, including DURAVYU; uncertainties and delays relating to communications with the U.S. Food and Drug Administration and the ability to obtain regulatory approval from FDA for the commercialization of DURAVYU; 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; disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA; changes in U.S. and international trade policies; 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; our ability to obtain additional funding to support our 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. A more complete discussion of the risks and uncertainties that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, in our other filings with the Securities and Exchange Commission (SEC) and in our future reports to be filed with the SEC, which are available at www.sec.gov. 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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