Aldeyra Therapeutics Receives Complete Response Letter from the U.S. Food and Drug Administration for the Reproxalap New Drug Application for the Treatment of Signs and Symptoms of Dry Eye Disease

March 17, 2026

LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 17, 2026-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) of reproxalap, an investigational drug candidate, for the treatment of dry eye disease. The CRL stated that there is “a lack of substantial evidence consisting of adequate and well-controlled investigations … that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling” and that “the application has failed to demonstrate efficacy in adequate and well controlled studies in the treatment of signs and symptoms of dry eye disease.” The letter also stated that the “inconsistency of study results raises serious concerns about the reliability and meaningfulness of the positive findings” and that the “totality of evidence from the completed clinical trials does not support the effectiveness of the product.” Consistent with prior NDA reviews of reproxalap, no safety or manufacturing concerns were identified.

During the NDA review, label drafts were provided by the FDA in December 2025 and again in March 2026. Aldeyra does not believe that label negotiations were completed.

The FDA recommended that the reasons for failure in certain trials be explored, and that populations or certain conditions in which reproxalap may be effective be identified. The FDA did not recommend conducting additional trials or request submission of additional confirmatory evidence. As such, Aldeyra does not currently expect to pursue additional clinical trials, and intends to expeditiously request a Type A meeting to understand the actions needed for NDA approval. Per Prescription Drug User Fee Act (PDUFA) goals, the target Type A meeting date is within 30 days of receipt of the meeting request.

“To the thousands of American and Canadian patients who participated in our clinical trials and to the tens of millions of patients with dry eye disease worldwide, I want to assure you that we will work with urgency to support the FDA in enabling market access to what is, to our knowledge, the only drug with clinical activity within minutes of administration in patients with dry eye disease, a condition that is today treated with medications that require weeks or months of treatment to achieve even modest improvement,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

As of December 31, 2025, Aldeyra reported cash, cash equivalents, and marketable securities of $70 million, which are expected to support operations into 2028.

About Aldeyra
Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. Our approach is to develop pharmaceuticals that modulate protein systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Our product candidates include RASP (reactive aldehyde species) modulators ADX-248, ADX-246, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our late-stage product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma and retinitis pigmentosa.

Safe Harbor Statement
This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Aldeyra’s future expectations, plans, and prospects, including without limitation statements regarding: the goals, opportunity, and potential for reproxalap; the outcome and expected timing of discussions with the FDA; and projected cash runway. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as, but not limited to, “may,” “might,” “will,” “objective,” “intend,” “should,” "could," “can,” “would,” “expect,” “believe,” “anticipate,” “project,” “on track,” “scheduled,” “target,” “design,” “estimate,” “predict,” “contemplates,” “likely,” “potential,” “continue,” “ongoing,” “aim,” “plan,” or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions, and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, funding, and other factors that could delay the initiation, enrollment, or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; delay in or failure to obtain regulatory approval of Aldeyra's product candidates, including as a result of the FDA not accepting Aldeyra’s regulatory filings, issuing a complete response letter, or requiring additional clinical trials or data prior to review or approval of such filings or in connection with resubmissions of such filings; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity, or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or different indications; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra’s ability to commercialize (alone or with others) and obtain reimbursement for Aldeyra's product candidates following

regulatory approval, if any; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and future revenue, the timing of future revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's commercialization, marketing and manufacturing capabilities and strategy; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; Aldeyra's expectations regarding federal, state, and foreign regulatory requirements; political, economic, legal, social, and health risks, public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2025, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, expected to be filed with the SEC in the second quarter of 2026, and Aldeyra's other filings with the SEC.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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