Aldeyra Therapeutics Announces Intent to Submit Formal Dispute Resolution Request for Reproxalap to Treat Dry Eye Disease

September 29, 2026

CONCORD, Mass.--(BUSINESS WIRE)--Sep. 29, 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 intent to submit to the U.S. Food and Drug Administration (FDA) a Formal Dispute Resolution Request (FDRR) for reproxalap, an investigational drug candidate, for the treatment of dry eye disease. The FDRR, which is expected to be reviewed by the FDA's Office of New Drugs (OND), is designed to appeal the March 16, 2026 Complete Response Letter that denied approval of a New Drug Application (NDA) for reproxalap for the treatment of dry eye disease. Submission of the FDRR and a meeting with the OND are expected in the fourth quarter of 2026.

Following an NDA submission and two NDA resubmissions of reproxalap for the treatment of dry eye disease, Aldeyra has received three Complete Response Letters, the first two of which recommended an additional clinical trial to "demonstrate a positive effect on the treatment of ocular symptoms of dry eye" and the most recent of which did not request further clinical trials but stated that the "totality of evidence from the completed clinical trials does not support the effectiveness of the product." Over the course of the three NDA submissions, Aldeyra has provided data from nine adequate and well-controlled clinical trials, five of which achieved all multiplicity-controlled primary endpoints, consistent with or greater than the success rates of clinical trials conducted for approved dry eye disease products.

The decision to submit the FDRR is based on the outcome of recent Type A and Type D meetings with the FDA Division of Ophthalmology and the Office of Specialty Medicine. Per Prescription Drug User Fee Act target timelines established for the FDRR process, Aldeyra expects to hold a meeting with OND in the fourth quarter of 2026. The timing of the OND FDRR decision will depend on a number of factors, including whether the deciding official requests additional information or determines there is a need to discuss the FDRR with internal or external experts or convene an advisory panel, the occurrence and timing of which are uncertain.

"We remain steadfast in our commitment to working with the FDA to provide a novel therapeutic approach for the treatment of dry eye disease, a condition often regarded by patients and physicians as inadequately addressed by available therapies," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra Therapeutics. "Based on the activity of reproxalap across a number of clinical trial designs, and against a backdrop of FDA dry eye disease product approvals that have applied considerable discretion, we are optimistic in the outcome of the FDRR."

Additionally, based on reported cash and cash equivalents of $45.1M as of June 30, 2026, Aldeyra updated financial guidance to include extension of operational cash runway into 2029.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss the FDRR. The dial-in numbers are (833) 461-5787 for domestic callers and (585) 542-9983 for international callers. The access code is 720 219 137. A live webcast of the conference call will be available on the Investor Relations page of the company's website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

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 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.

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; the timing and outcome of the expected FDRR submission; and projected operational 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 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, which are 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 September 30, 2026, expected to be filed with the SEC in the fourth 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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Investor & Media Contact:
David Burke
(917) 618-2651
investorrelations@aldeyra.com

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