

**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): May 6, 2025 (May 5, 2025)

ALDEYRA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36332
(Commission
File No.)

20-1968197
(IRS Employer
Identification No.)

131 Hartwell Avenue, Suite 320
Lexington, MA 02421
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable
(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, \$0.001 par value per share	ALDX	The Nasdaq Stock Market LLC

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 7.01. Regulation FD Disclosure.

On May 5, 2025, Aldeyra Therapeutics, Inc. (the “Company”) issued a press release (the “Press Release”) to announce the achievement of the primary endpoint of ocular discomfort in the Phase 3 dry eye chamber trial of 0.25% reproxalap ophthalmic solution, an investigational new drug candidate for the treatment of dry eye disease, and the plan to resubmit a New Drug Application. The Company is holding a conference call regarding the announcement on May 6, 2025. A copy of the supplemental presentation which will be referenced during the conference call and posted on the Company’s website is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

As reported under Item 7.01 of this Current Report on Form 8-K, on May 5, 2025, the Company issued the Press Release to announce the achievement of the primary endpoint of ocular discomfort in the Phase 3 dry eye chamber trial of 0.25% reproxalap ophthalmic solution, an investigational new drug candidate for the treatment of dry eye disease, and the plan to resubmit a New Drug Application. The Press Release is filed herewith as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Aldeyra Therapeutics, Inc. Presentation dated May 6, 2025
99.2	Aldeyra Therapeutics, Inc. Press Release dated May 5, 2025
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.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady
Name: Todd C. Brady, M.D., Ph.D.
Title: Chief Executive Officer

Dated May 6, 2025



REPROXALAP FOR THE POTENTIAL
TREATMENT OF DRY EYE DISEASE

Topline Data Release and NDA Resubmission Plan

May 6, 2025

Nasdaq: ALDX

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Disclaimers and Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, statements regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding: Aldeyra's cash runway; the outcome and expected timing of discussions with the FDA; FDA agreement with the clinical development and regulatory plan for reproxalap; the outcome and expected timing and results of the clinical development and regulatory plan; the outcome and timing of the FDA's acceptance, review and/or approval of a potential NDA resubmission for reproxalap and the adequacy of the data included in the potential NDA resubmission or the supplemental responses to the FDA; the potential for and timing of regulatory approval and commencement of commercialization of reproxalap; Aldeyra's expectations regarding the exercise of the AbbVie option; the potential profile and benefit of reproxalap in dry eye disease and allergic conjunctivitis and its other product candidates in the indications for which they are developed; the goals, opportunity and potential for reproxalap and its other product candidates, anticipated clinical or regulatory milestones for ADX-2191, ADX-248, ADX-743, ADX-631, ADX-629 and ADX-246, including expectations regarding the results of scheduled FDA meetings and discussions, clinical trial initiations and completions, and the timing and nature of NDA or other submissions to the FDA; Aldeyra's business, research, development and regulatory plans or expectations; political, economic, legal, social and health risks that may affect Aldeyra's business or the global economy; the structure, timing and success of Aldeyra's planned or pending clinical trials; and expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environment and potential growth opportunities, among other things. The results of earlier preclinical or clinical trials may not be predictive of future results. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development of, and clinical and regulatory plans or expectations for Aldeyra's investigational new drugs (including reproxalap, ADX-2191, ADX-629, ADX-248, ADX-743, ADX-631, and ADX-246), and systems-based approaches, later developments with the FDA that may be inconsistent with Aldeyra's expectations and beliefs, including the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial for the same or different indications, inconsistent expectations regarding FDA acceptance and review of the company's filings and submitted data sets, and Aldeyra's continuing or post-hoc review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in Aldeyra's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as Aldeyra's subsequent filings with the Securities and Exchange Commission. All of Aldeyra's development plans and timelines may be subject to adjustment depending on funding, recruitment rate, regulatory review, which regulatory review timeline may be flexible and subject to change based on the regulator's workload and other potential review issues, preclinical and clinical results, regulatory developments in the United States and other countries, and other factors any of which could result in changes to Aldeyra's development plans and programs or delay the initiation, enrolment, completion, or reporting of clinical trials.

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 presentation is provided only as of May 06, 2025, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.



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Based on New Clinical Trial Results, Aldeyra Intends to Resubmit the NDA of Reproxalap for the Potential Treatment of Dry Eye Disease[†]

On April 3, 2025, Aldeyra announced the receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) of reproxalap for the potential treatment of dry eye disease. The CRL stated that the NDA “failed to demonstrate efficacy in adequate and well controlled studies in treating ocular symptoms associated with dry eyes” and that “at least one additional adequate and well controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye” should be conducted. The letter identified concerns with the data from the dry eye chamber trial submitted to the NDA that may have affected interpretation of the results, which the FDA stated may be related to methodological issues, including a difference in baseline scores across treatment arms.

Following the CRL, Aldeyra requested and received feedback from the FDA on two ongoing clinical trials designed to assess the effect of reproxalap on the symptoms of dry eye disease: a dry eye chamber trial and a field trial.

The dry eye chamber trial, which was substantially similar to the dry eye chamber trial previously submitted, achieved statistical significance in favor of reproxalap over vehicle ($P=0.002$). There were no notable differences in baseline scores observed across treatment arms. While reproxalap was numerically superior to that of vehicle in the field trial, the effect was not statistically significant.

Aldeyra has requested a Type A meeting to discuss potential NDA resubmission based on the recently completed dry eye chamber trial, which Aldeyra believes potentially addresses the FDA feedback outlined in the CRL.

 [†] NDA resubmission requirements depend, in part, on regulatory feedback. Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload and other potential review issues. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the U.S. Food and Drug Administration; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

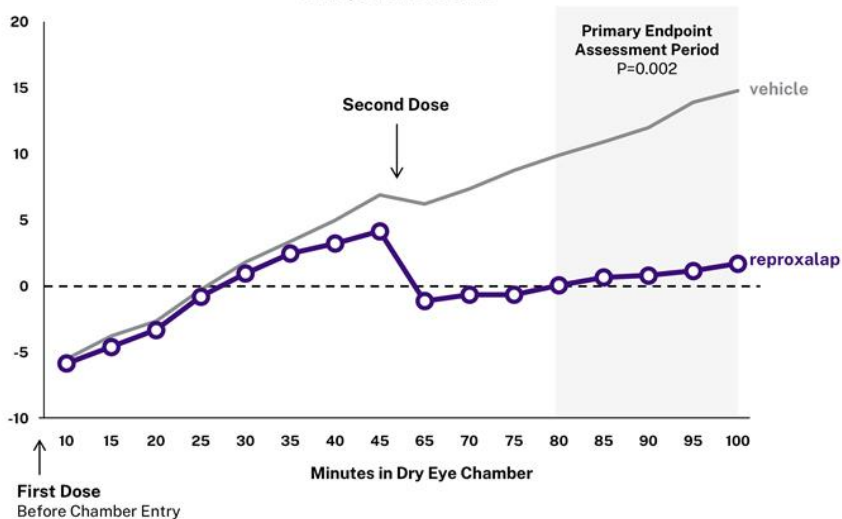
The Phase 3 Dry Eye Chamber Trial Achieved the Primary Endpoint of Ocular Discomfort

The vehicle increase from baseline was more than


8x

higher than that of reproxalap.

Mean Ocular Discomfort Score (0-100)
Change from Baseline

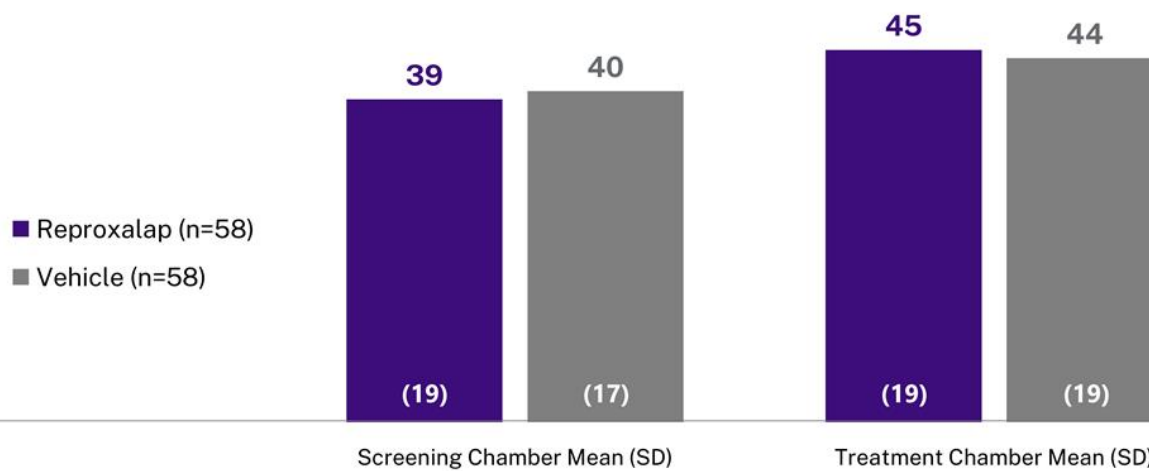


Aldeyra believes that the results are supportive of the potential rapid clinical effect of reproxalap on reducing ocular discomfort, and potentially addresses the FDA feedback following the prior NDA review of a previously completed dry eye chamber trial.

 P value derived from primary endpoint mixed model for repeated measures analysis. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the U.S. Food and Drug Administration; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. NDA=New Drug Application

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In the Recently Completed Dry Eye Chamber Trial, Ocular Discomfort Baselines Were Balanced Across Treatment Arms

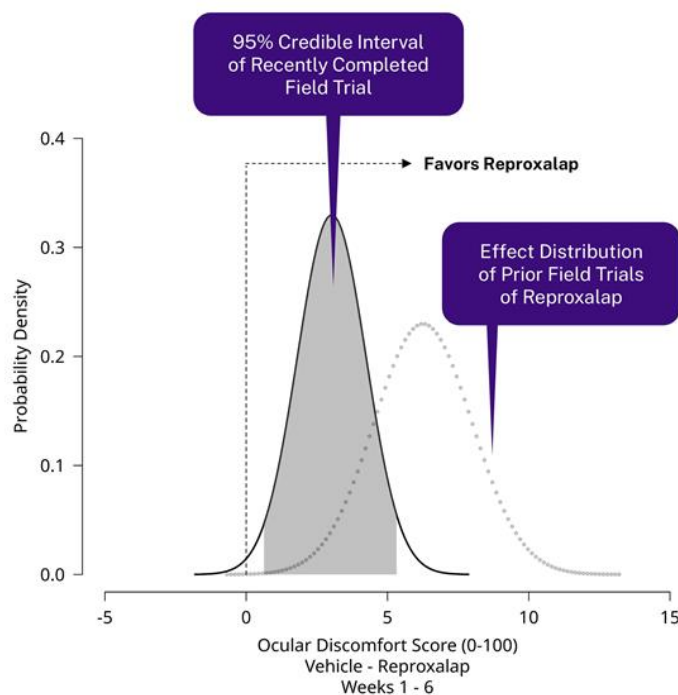


Topical ocular reproxalap is an investigational drug candidate that has not been approved by the U.S. Food and Drug Administration; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. SD=standard deviation

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The Recently Completed Field Trial Results, which Were Numerically Supportive of Reproxalap and Consistent with Prior Field Trials, Did Not Reach Statistical Significance

The Bayesian model of probable effect was used post hoc to estimate the probability of superiority of reproxalap over vehicle in conjunction with prior field trial results.



Reproxalap Represents a Novel Potential Therapeutic Approach in Dry Eye Disease with Rapid Activity in Clinical Trials

Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.



Rapid and sustained symptom improvement



Broad symptomatic activity



Acute reduction of ocular redness

Dry eye disease afflicts 39 million or more adults in the United States.[†]



[†]Company estimates and Am J Ophthalmol. 2014;157(4):799-806. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the U.S. Food and Drug Administration; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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Aldeyra Believes the Positive Results from the Phase 3 Dry Eye Chamber Trial Enable Potential NDA Resubmission[†] of Reproxalap for the Potential Treatment of Dry Eye Disease

1

We believe that the results from the recently completed dry eye chamber trial, including no notable differences in baseline scores across treatment arms, potentially address the FDA feedback following the prior NDA review of a previously completed dry eye chamber trial.

2

Pending the Type A meeting with the FDA, NDA resubmission is anticipated in mid-2025.

3

The anticipated review period for the potential NDA resubmission is expected to be six months.



[†]NDA resubmission requirements depend, in part, on regulatory feedback. Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload and other potential review issues. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the U.S. Food and Drug Administration; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. NDA=New Drug Application; FDA=U.S. Food & Drug Administration

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Clinical and Regulatory Milestones

[†]The timing of clinical trials depends, in part, on the availability of clinical research facilities and staffing, the ability to recruit patients, and the number of patients in the trial. ^{*}Investigator sponsored.

- Dry Eye Disease (Reproxalap)**
Completion of Field and Chamber Trials
- Dry Eye Disease (Reproxalap)**
Potential NDA Resubmission Expected Mid-2025
- Allergic Conjunctivitis (Reproxalap)**
Positive Phase 3 INVIGORATE 2 trial top-line results announced
- Atopic Dermatitis (ADX-248)**
Phase 1 clinical trial initiated[†]
- Moderate Alcohol-Associated Hepatitis (ADX-629)**
Open-label Phase 2 clinical trial top-line results expected in 2025[†]
- Retinitis Pigmentosa (ADX-2191)**
Phase 2/3 clinical trial initiation expected in 2025[†]
- Dry Age-Related Macular Degeneration/Geographic Atrophy (ADX-631/ ADX-246)**
Investigational New Drug application expected to be submitted in 2025
- Sjögren-Larsson Syndrome (ADX-629)***
Phase 2 clinical trial pediatric cohort top-line results expected in 2025
- Obesity/Hypertriglyceridemia (ADX-743)**
Investigational New Drug application expected to be submitted in 2025





**Aldeyra Therapeutics Achieves Primary Endpoint in Phase 3 Dry Eye Disease Chamber Trial of Reproxalap and Plans NDA Resubmission
In a Dry Eye Chamber Trial, Reproxalap Was Statistically Superior (P=0.002) to Vehicle in Primary Endpoint of Ocular Discomfort
Aldeyra Believes the Dry Eye Chamber Trial Results, including No Notable Differences in Baseline Scores Across Treatment Arms, Potentially
Address FDA Feedback following the Prior NDA Review
New Drug Application Resubmission Is Anticipated Mid-2025**

**A Recently Completed Dry Eye Disease Field Trial, which Was Numerically Supportive of Reproxalap and Consistent with Prior Field Trials,
Did Not Reach Statistical Significance, and Is Expected to be Submitted to the Planned NDA Resubmission as Supportive**

Lexington, Mass., May 5, 2025 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated and metabolic diseases, today announced the achievement of the primary endpoint in a Phase 3 randomized, double-masked, vehicle-controlled dry eye chamber trial of 0.25% reproxalap ophthalmic solution, an investigational new drug candidate, for the treatment of dry eye disease. For the prespecified primary endpoint of ocular discomfort, a symptom of dry eye disease, reproxalap (n=58) was statistically significantly superior to vehicle (n=58) on ocular discomfort symptom score (0-100) from 80 to 100 minutes after chamber entry (LS mean difference [95% confidence interval] -6.5 [-10.5, -2.5], P=0.002).

Aldeyra believes that the dry eye chamber trial results, which included no notable differences in baseline scores across treatment arms, potentially address the U.S. Food and Drug Administration (FDA) feedback in a Complete Response Letter received in April 2025 in response to the prior New Drug Application (NDA). The Complete Response Letter identified concerns with a previously completed dry eye chamber trial that may have affected the interpretation of the results, including a baseline difference across treatment arms. Pending a Type A meeting with the FDA, NDA resubmission is anticipated mid-2025, and the review period is expected to be six months. A recently completed dry eye disease field trial, which was numerically supportive of reproxalap and consistent with prior field trials, did not reach statistical significance, and is expected to be submitted to the planned NDA resubmission as supportive.

“The dry eye chamber results announced today are representative of a number of clinical trials that highlight the potential rapid clinical effect of reproxalap on reducing ocular discomfort,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “With no notable baseline differences across treatment arms and highly statistically significant results in favor of reproxalap over vehicle, Aldeyra believes the data potentially address the FDA feedback in the Complete Response Letter received last month and we look forward to meeting with the FDA shortly.”

To Aldeyra’s knowledge, in patients with dry eye disease, reproxalap is the first investigational drug with pivotal data supportive of acute and chronic activity in reducing symptoms, and the first investigational drug for chronic administration with pivotal data supportive of acute activity in reducing exacerbation of ocular redness. There were no safety signals or treatment-related discontinuations observed in either of the recently completed clinical trials, and reproxalap was observed to be well tolerated. Consistent with prior clinical trials, the most commonly reported adverse event was mild and transient instillation site discomfort. Reproxalap has now been studied in over 2,900 patients.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET tomorrow, May 6, 2025, to discuss the clinical trial results and the plan for resubmission of the NDA for reproxalap in dry eye disease. The dial-in numbers are (833) 470-1428 for domestic callers and (404) 975-4839 for international callers. The access code is 127477. 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 Reproxalap

Reproxalap is an investigational new drug candidate in development for the treatment of dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology. Reproxalap is a first-in-class small-molecule modulator of RASP, which are elevated in ocular and systemic inflammatory diseases. The mechanism of action of reproxalap has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap has been studied in more than 2,900 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

About Aldeyra

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated and metabolic 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-629, ADX-248, ADX-743, ADX-631, ADX-246, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated and metabolic 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 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; the potential and the timing of a potential NDA resubmission; the outcome and timing of the FDA's acceptance, review, or approval of the potential NDA resubmission for reproxalap and the adequacy of the data included in the initial NDA and resubmitted NDA, and expected to be included in the potential resubmitted NDA; the likelihood and timing of the exercise of the Option; and Aldeyra's expectations regarding the labeling for reproxalap, if approved. 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; 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, 2024, 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, 2025, expected to be filed with the SEC in the second quarter of 2025, 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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