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): November 28, 2023 (November 27, 2023)

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

Delaware	001-36332	20-1968197
(State or other jurisdiction of incorporation)	(Commission File No.)	(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.

As reported under Item 8.01 of this Current Report on Form 8-K, on November 27, 2023, Aldeyra Therapeutics, Inc. ("Aldeyra" or the "Company") issued a press release (the "Press Release") to provide a regulatory update regarding reproxalap, an investigational drug candidate, for the treatment of dry eye disease. The Company will hold a conference call regarding this announcement on November 28, 2023. 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 to this Current Report on Form 8-K 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.

On November 27, 2023, Aldeyra issued the Press Release to announce that it had received a Complete Response Letter ("Complete Response Letter") from the U.S. Food & Drug Administration ("FDA") regarding the Company's New Drug Application ("NDA") for reproxalap, an investigational drug candidate, for the treatment of dry eye disease. In the Complete Response Letter, the FDA stated that the NDA did not demonstrate "efficacy 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. On November 16, 2023, Aldeyra submitted to the FDA a Special Protocol Assessment ("SPA") for a dry eye disease chamber crossover clinical trial similar to the crossover chamber trial from which Aldeyra announced results on July 12, 2022. The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

The following risk factor is provided to supplement Aldeyra's risk factors previously disclosed under the heading "Risk Factors" in Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2022 and Aldeyra's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023, June 30, 2023, and September 30, 2023.

Aldeyra's success in obtaining regulatory approval of reproxalap from the FDA depends on Aldeyra's ability to address the issues raised by the FDA in the Complete Response Letter, and address any issues the FDA may raise in the future.

Aldeyra submitted an NDA for reproxalap for the treatment of the signs and symptoms of dry eye disease in December 2022. In February 2023, the FDA accepted the reproxalap NDA for filing and set a Prescription Drug User Fee Act date of November 23, 2023. On November 27, 2023, Aldeyra announced that it had received a Complete Response Letter from the FDA. In the Complete Response Letter, the FDA stated that the NDA did not demonstrate "efficacy 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. On November 16, 2023, prior to receiving the Complete Response Letter, Aldeyra submitted to the FDA a Special Protocol Assessment ("SPA") for a dry eye disease chamber crossover clinical trial (the "proposed trial"), which could potentially result in data acceptable for FDA review towards a potential NDA resubmission for reproxalap for the treatment of the signs and symptoms of dry eye disease. A SPA is an advanced declaration from the FDA that a planned trial's design, clinical endpoints, and statistical analyses could potentially result in data acceptable for FDA review towards approval for the proposed indication. Aldeyra expects the next steps will include receiving feedback from the FDA on the SPA and initiating the proposed trial. There can be no assurance that the SPA feedback from the FDA will be positive. Without the concurrence of the FDA on a SPA or otherwise, Aldeyra cannot be certain that the design, conduct, and analysis of the results of the proposed trial will be sufficient to establish the effectiveness of reproxalap for treatment of dry eye disease to the FDA's satisfaction, and therefore allow Aldeyra to resubmit or receive approval of a NDA for reproxalap. As part of the SPA or in connection with its review of the potential NDA resubmission, the FDA could require additional studies or clinical trials, and the submission of the results of those studies or clinical trials before a potential NDA resubmission will be

reconsidered, which would require Aldeyra to expend more resources than Aldeyra planned or that are available to Aldeyra, and could substantially delay acceptance and/or approval, if any, of a potential NDA resubmission. Any such requirement would increase Aldeyra's costs and delay approval and commercialization of reproxalap for the treatment of dry eye disease and would have a material adverse effect on Aldeyra's business and financial condition.

Even if reproxalap is approved for the treatment of dry eye disease, the FDA may limit use to certain patient populations, include extensive warnings on the product labeling, or require costly ongoing requirements for post-marketing clinical studies and surveillance or other risk management measures to monitor the safety or efficacy of reproxalap.

Any regulatory approval of reproxalap, in addition to the FDA's feedback on the SPA, once obtained, may be withdrawn. Ultimately, the failure to obtain and maintain regulatory approvals would prevent reproxalap from being marketed and would have a material adverse effect on Aldeyra's business.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the outcome and timing of the FDA's review of and feedback on the SPA; the FDA's potential acceptance and/or approval of a potential NDA resubmission for reproxalap; the adequacy of the data of the proposed trial or other additional studies or clinical trials conducted in connection with the SPA; a potential NDA resubmission or the supplemental responses to the FDA; and the Company's ability to successfully commercialize (alone or with others) reproxalap. Any statements about the Company's expectations, beliefs, plans, predictions, forecasts, objectives, assumptions, or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "believes," "can," "could," "may," "predicts," "potential," "should," "will," "estimate," "plans," "projects," "continuing," "ongoing," "expects," "intends," and similar words or phrases. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, these statements are not guarantees of future performance and involve risks and uncertainties which are subject to change based on various important factors, some of which are beyond the Company's control. The Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Current Report on Form 8-K and are subject to a number of risks, uncertainties and assumptions including, without limitation, risks and factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2023, expected to be filed with the SEC in the first quarter of 2024. The Company does not undertake any obligation to update any forward-looking statements made in this Current Report on Form 8-K as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Presentation dated November 28, 2023
99.2	Aldeyra Therapeutics, Inc. Press Release dated November 27, 2023
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 November 28, 2023

Exhibit 99.1

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CONFERENCE CALL

Reproxalap for the Treatment of Dry Eye Disease Regulatory Update

November 28, 2023

Nasdaq: ALDX

Disclaimers and Forward-Looking Statements

This presentation and various remarks which may be made during this presentation contain 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: the outcome and expected timing of the FDA's review of and feedback on the SPA; the outcome and expected timing and results of the proposed dry eye disease chamber crossover clinical trial; the outcome and timing of the FDA's review, acceptance, 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 regulatory approval and commencement of commercialization of reproxalap and Aldeyra's goals as to timing; 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-246, ADX-248, and ADX-629 including expectations regarding the results of scheduled FDA meetings, clinical trial initiations and completions and 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 and ADX-2191), 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, 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 November 28, 2023, 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.

Aldeyra Received a Complete Response Letter for Reproxalap for the Treatment of Dry Eye Disease

The letter stated that the NDA did not demonstrate "efficacy 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.

Per draft FDA guidance, efficacy in dry eye disease may be demonstrated with two symptom trials and two sign trials.

Among other clinical trials, Aldeyra previously conducted two trials for ocular redness (a dry eye disease sign) as well as a dry eye disease symptom trial.

No chemistry, manufacturing and controls or safety issues were identified.

Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

Aldeyra Has Proposed to the FDA a Symptom Trial to Satisfy Efficacy Requirements for Reproxalap in Dry Eye Disease

A Special Protocol Assessment (SPA) was submitted to the FDA on November 16, 2023, for a dry eye disease chamber crossover clinical trial (the proposed trial) similar to the crossover chamber trial from which Aldeyra announced results on July 12, 2022. The SPA review cycle is anticipated to be 45 days.

The proposed trial is expected to cost less than $2M, the primary endpoints are symptoms, and top-line results are anticipated in the first half of 2024, subject to FDA feedback on the SPA.

Pending FDA feedback on the SPA, successful results from the proposed trial are expected to allow for potential resubmission of the New Drug Application (NDA) in the first half of 2024. The NDA review is anticipated to be six months.

If the SPA and proposed trial results are successful, Aldeyra intends to resubmit the NDA with a draft drug label describing a combination of chronic and acute symptomatic benefit, as well as acute reduction in ocular redness.

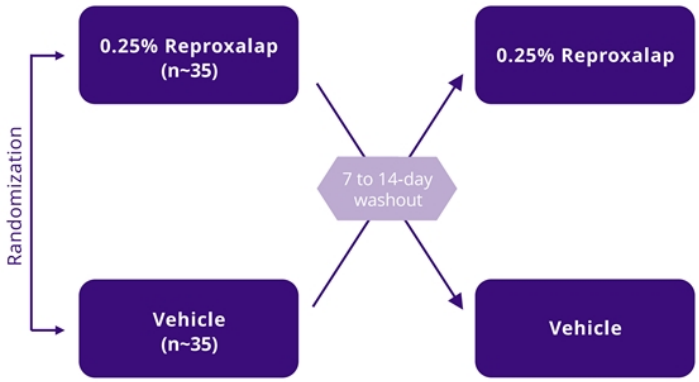
Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. The timing of clinical trials depends, in part, on FDA feedback on the SPA, the availability of clinical research facilities and staffing, and the ability to recruit patients. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

The Proposed Crossover Chamber Trial Design is Materially Identical to the Previously Completed Dry Eye Chamber Trial

Design	Randomized, double-masked, crossover, vehicle-controlled, single-center
Dosing	0.25% reproxalap or vehicle, 7 to 14-day washout Day 1: four doses Day 2: one dose before 90-minute dry eye chamber, one dose 45 minutes after chamber entry
Expected Size	70 patients
Primary Endpoints[†]	• Subject-reported eye dryness score • Subject-reported ocular discomfort score
Secondary Endpoints	• Subject-reported ocular burning score • Subject-reported ocular grittiness score • Subject-reported ocular stinging score

Treatment Visits

Each treatment visit represents Day 1 (pre-chamber) and Day 2 (chamber) visits.

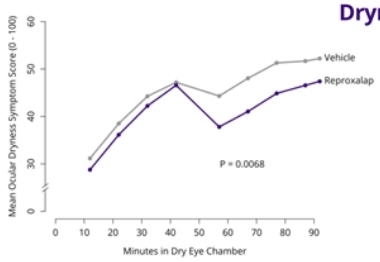


Top-line results expected in the first half of 2024

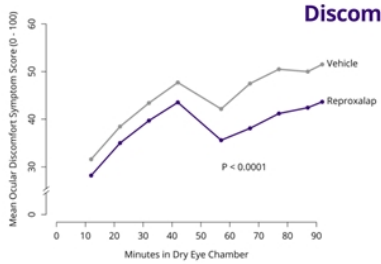
[†] The Hochberg procedure is expected to be used to control for multiplicity. Unused alpha from the Hochberg procedure is expected to be passed to a fixed sequence of secondaries, to be tested in the order listed. The timing of clinical trials depends, in part, on FDA feedback on the SPA, the availability of clinical research facilities and staffing, and the ability to recruit patients. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

Acute Improvement Was Demonstrated for All Symptoms Assessed in the Previously Completed Dry Eye Chamber Crossover Trial

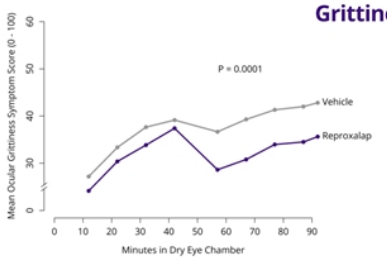
Dryness



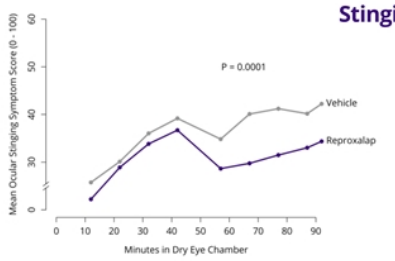
Discomfort



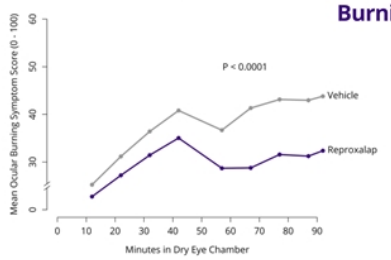
Grittiness



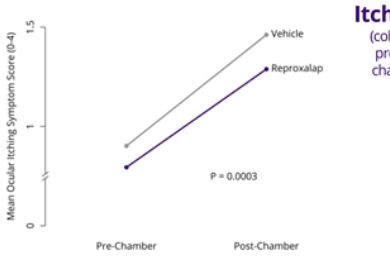
Stinging



Burning



Itching (collected pre/post chamber only)



Symptoms were assessed as secondary endpoints that were not multiplicity controlled. P values derived from mixed effect model of repeated measures of change from baseline. Source: Dry eye disease crossover clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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Aldeyra is Well Positioned to Execute on Potential NDA Resubmission Milestones

With $143M in cash, cash equivalents, and marketable securities as of September 30, 2023, Aldeyra is well positioned to execute on potential NDA resubmission milestones:

SPA feedback anticipated in December 2023

Dry eye disease chamber crossover clinical trial top-line results expected in the first half of 2024, pending SPA feedback

Potential NDA resubmission anticipated in the first half of 2024, pending FDA SPA feedback and positive trial results

Review period for the potential NDA resubmission expected to be six months

Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. The timing of clinical trials depends, in part, on FDA feedback on the SPA, the availability of clinical research facilities and staffing, and the ability to recruit patients. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

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

- **Additional Trial Required to Demonstrate Positive Effect on the Treatment of Ocular Symptoms in Dry Eye Disease**
- **Special Protocol Assessment Submitted on November 16, 2023 for Dry Eye Disease Chamber Crossover Clinical Trial**
- **Proposed Trial Top-Line Results and Potential NDA Resubmission Anticipated in First Half of 2024**
- **Cash Runway Extended into Late 2025**

Lexington, Mass., November 27, 2023 – 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 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. Although no safety or manufacturing issues with reproxalap were identified, the FDA stated in the letter that the NDA did not demonstrate "efficacy 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.

Per draft FDA dry eye disease guidance, efficacy in dry eye disease may be demonstrated with two symptom trials and two sign trials. Among other clinical trials, Aldeyra previously conducted two trials for ocular redness (a dry eye disease sign) as well as a dry eye disease symptom trial. On November 16, 2023, Aldeyra submitted to the FDA a Special Protocol Assessment (SPA) for a dry eye disease chamber crossover clinical trial (the proposed trial) similar to the crossover chamber trial from which Aldeyra announced results on July 12, 2022. The SPA review cycle is anticipated to be 45 days, and Aldeyra expects FDA feedback from the SPA in December of 2023. The proposed trial is expected to cost less than $2 million, and top-line results are anticipated in the first half of 2024, subject to FDA feedback on the SPA.

The potential NDA resubmission is anticipated in the first half of 2024, pending FDA SPA feedback and positive results from the proposed trial. Aldeyra intends to include in the potential NDA resubmission a draft label describing chronic and acute symptomatic benefit, in addition to acute reduction in ocular redness of reproxalap. The review period for the potential NDA resubmission is expected to be six months.

“With $143 million in cash, cash equivalents, and marketable securities as of September 30, 2023, we are well positioned to conduct another symptom trial of reproxalap in patients with dry eye disease, with a potential NDA resubmission in the first half of 2024,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra Therapeutics. “If the SPA and proposed trial results are successful, and the potential resubmitted NDA is approved, the drug label may be the first label in dry eye disease to contain acute reduction in ocular redness, as well as a combination of chronic and acute symptomatic benefit, potentially highlighting the rapid activity of reproxalap on both signs and symptoms of dry eye disease.”

Reproxalap is also under development for the treatment of allergic conjunctivitis, a common inflammatory disease that affects an estimated 20% of the worldwide population. Results from the third positive Phase 3 clinical trial of reproxalap in allergic conjunctivitis, the INVIGORATE-2 Trial, were announced on June 15, 2023. Aldeyra plans to conduct a Type C meeting with the FDA in the first half of 2024 to discuss the potential NDA submission of reproxalap for the treatment of allergic conjunctivitis.

Aldeyra is extending previous cash runway guidance into late 2025, including clinical trial costs associated with the proposed trial and potential NDA resubmission; the initial commercialization and launch plans for reproxalap, if approved in late 2024; and continued early and late-stage development of its product candidates in ocular and systemic immune-mediated diseases. The extended cash runway guidance is based on Aldeyra’s current operating plan, which excludes any potential licensing or product revenue associated with reproxalap.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET tomorrow, November 28, 2023, to provide a regulatory update on reproxalap. The dial-in numbers are (833) 470-1428 for domestic callers and (404) 975-4839 for international callers. The access code is 334884. A live audio webcast of the conference call also will be accessible from the “Investors & Media” section of Aldeyra’s website at ir.aldeyra.com. 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 immunological 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-246, ADX-248, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our pre-commercial 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 proliferative vitreoretinopathy and retinitis pigmentosa.

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 (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. 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 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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 the outcome and timing of the FDA's potential feedback on the SPA; the outcome and expected timing and the results of the proposed trial (as defined above); the outcome and timing of the FDA's review, acceptance and/or approval of a potential NDA resubmission for reproxalap and the adequacy of the data included in the original NDA and the potential NDA resubmission; Aldeyra's expectations regarding the labeling for reproxalap, if approved; Aldeyra's projected cash runway; Aldeyra's ability to successfully commercialize (alone or with others) reproxalap; Aldeyra's expectations regarding the development of reproxalap for the treatment of allergic conjunctivitis; and Aldeyra's expectations regarding timing and results of potential or scheduled FDA meetings, including the planned Type C meeting with the FDA to discuss the development of reproxalap for the treatment of allergic conjunctivitis. 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 reproxalap or Aldeyra's other product candidates, including as a result of the FDA not accepting Aldeyra's regulatory filings, issuing a complete response letter, providing feedback and/or rejecting the SPA, 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, 2022, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, 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 Annual Report on Form 10-K for the year ended December 31, 2023, expected to be filed with the SEC in the first quarter of 2024, 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.

Investor & Media Contact:

David Burke
Tel: (917) 618-2651
investorrelations@aldeyra.com