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): August 8, 2024

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.

On August 8, 2024, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") to announce the achievement of the primary endpoint of ocular discomfort from the Phase 3 dry eye chamber clinical trial of 0.25% reproxalap ophthalmic solution, an investigational new drug candidate, for the treatment of dry eye disease. The Company is holding a conference call regarding the announcement on August 8, 2024. 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 August 8, 2024, the Company issued the Press Release to announce the achievement of the primary endpoint of ocular discomfort from the Phase 3 dry eye chamber clinical trial of 0.25% reproxalap ophthalmic solution, an investigational new drug candidate, for the treatment of dry eye disease. 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

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Presentation dated August 8, 2024
99.2	Aldeyra Therapeutics, Inc. Press Release dated August 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

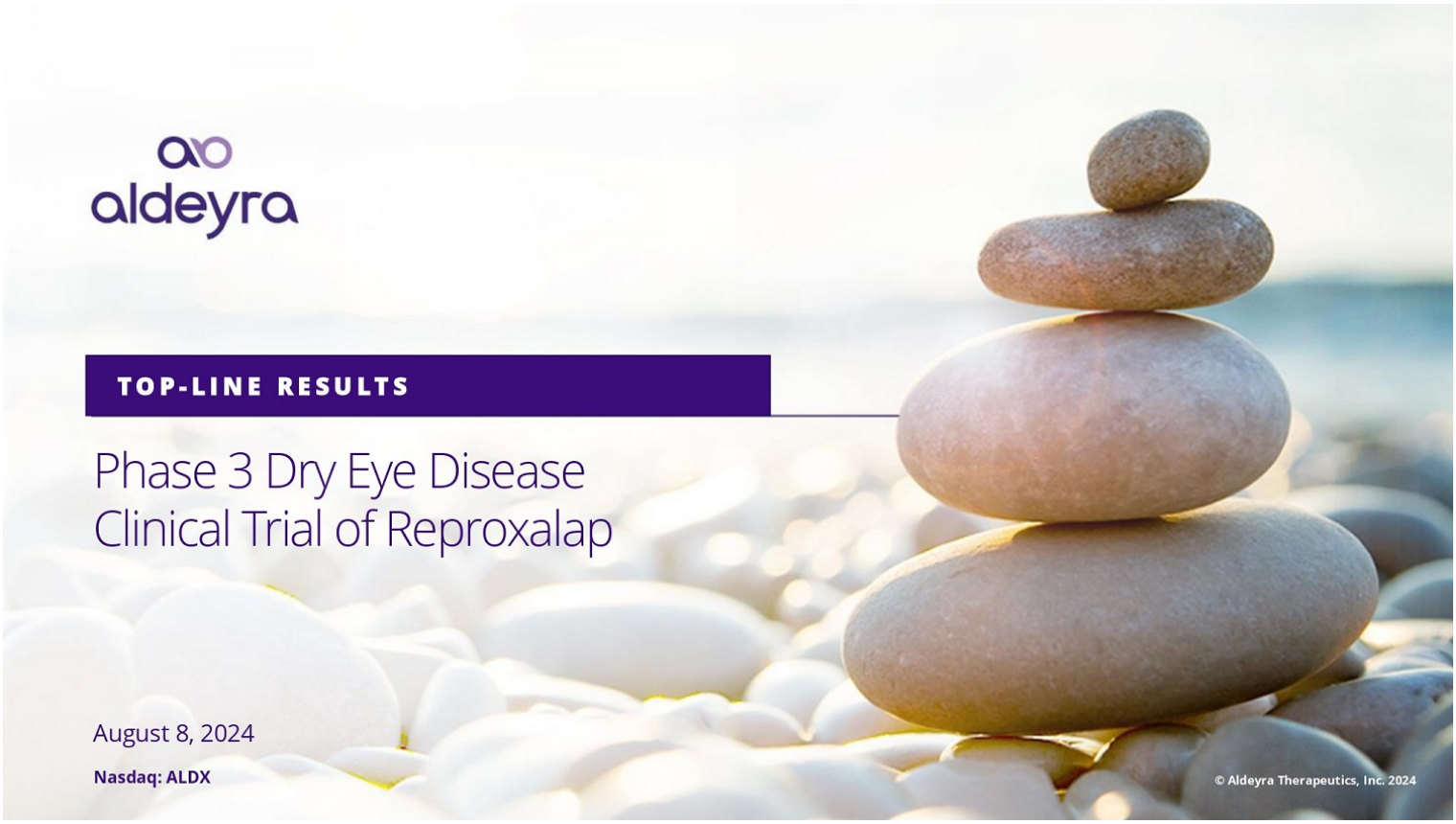
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALDEYRA THERAPEUTICS, INC.

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

Dated August 8, 2024

Exhibit 99.1


aldeyra
TOP-LINE RESULTS
Phase 3 Dry Eye Disease
Clinical Trial of Reproxalap
August 8, 2024
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: FDA agreement with the clinical development and regulatory plan for reproxalap; 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 and timing of regulatory approval; Aldeyra's expectations regarding the exercise of the AbbVie Option; Aldeyra's goals as to 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; anticipated clinical or regulatory milestones for ADX-2191, ADX-248, ADX-743, ADX-631, and ADX-629, 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-248, ADX-743, ADX-631, and ADX-629), 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 August 8, 2024, 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.

Reproxalap is an investigational new drug and is not available for commercial distribution.

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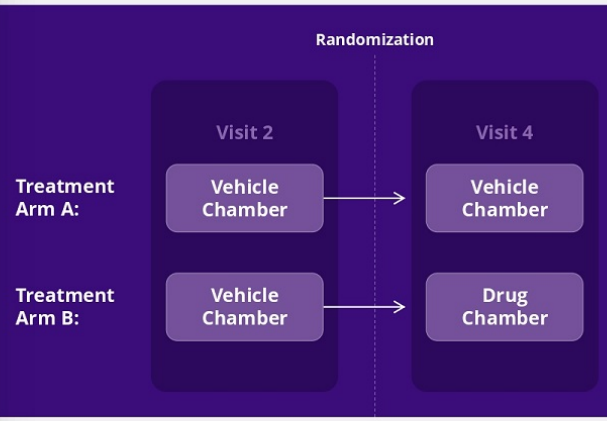
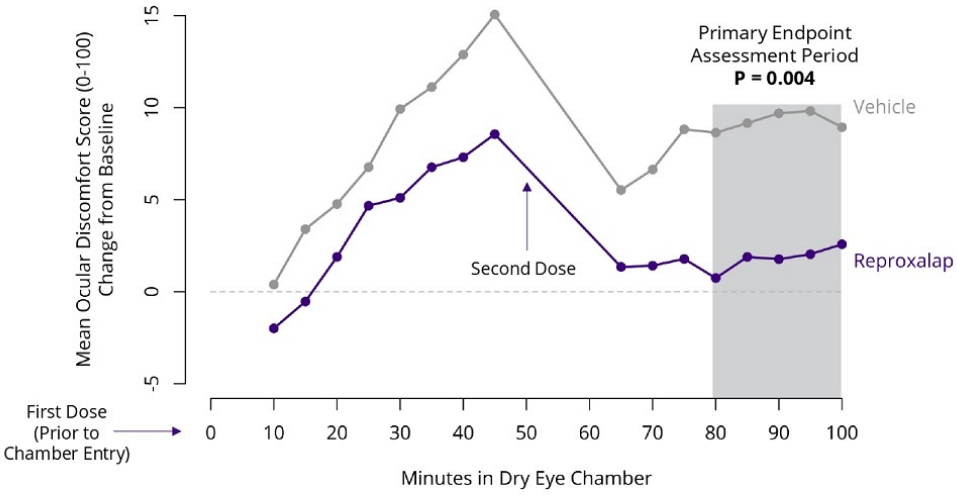
The Phase 3 Clinical Trial of Reproxalap in a Dry Eye Chamber was Designed to Satisfy the Requirements for NDA Resubmission†

Design	• Randomized, double-masked, vehicle-controlled dry eye chamber challenge
Dosing	• Visit 1: Medical screening • Visit 2: Vehicle dry eye chamber (dosing just before and 50 minutes after entry) • Visit 3: Four doses of randomized treatment (reproxalap or vehicle) • Visit 4: Randomized dry eye chamber (dosing just before and 50 minutes after entry)
Size	132 dry eye disease patients: 66 randomized to reproxalap, 66 randomized to vehicle
Primary Endpoint	Ocular discomfort score from 80 to 100 minutes
Other Endpoints	Safety



†NDA submission 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 new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. NDA = New Drug Application.

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



To our knowledge, the results represent the first positive Phase 3 clinical trial in a dry eye chamber with a symptom as a primary endpoint, and we believe that the results are supportive of the potential rapid clinical effect of reproxalap on reducing ocular discomfort.

P value derived from primary endpoint mixed model for repeated measures analysis. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 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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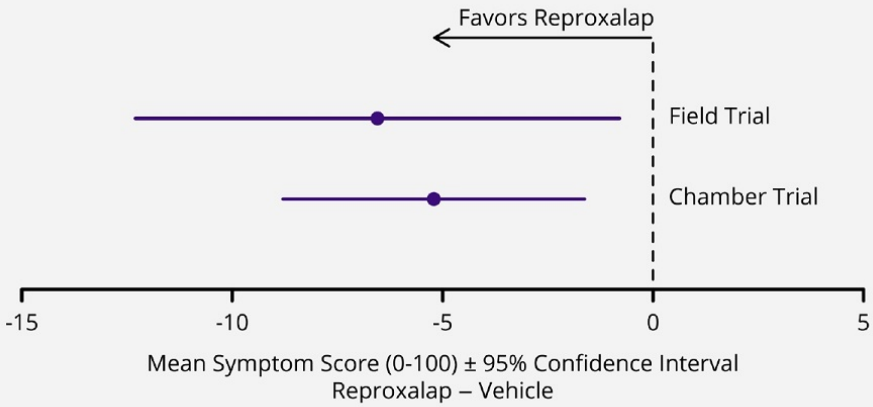
Aldeyra Believes that Symptom Requirements for Dry Eye Disease NDA Resubmission† Have Been Met



The Phase 3 dry eye chamber clinical trial symptom results are consistent with field trial symptom results previously reviewed by the FDA.

†NDA submission 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. Estimates based on primary endpoint mixed model for repeated measures analyses. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; 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.

Aldeyra Believes that Positive Results from the Phase 3 Clinical Trial Enable NDA Resubmission† of Reproxalap for Dry Eye Disease

- The dry eye chamber clinical trial was designed to satisfy the FDA's single resubmission requirement of "at least one additional adequate and well-controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye."
- Through the Special Protocol Assessment process and additional comments, the FDA provided feedback on the clinical trial protocol and statistical plan.
- Aldeyra believes the Phase 3 clinical trial satisfies the FDA's NDA resubmission requirement. NDA resubmission is anticipated in 2024. Based on FDA guidance, the anticipated review period for the potential NDA resubmission is expected to be six months.

†NDA submission 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 new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; 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.

Aldeyra has Entered into an Exclusive Option Agreement with AbbVie Inc. for License to Develop and Commercialize Reproxalap

Key Terms of Reproxalap Option Agreement

Option for AbbVie to obtain:

- Co-exclusive license to develop, manufacture, and commercialize reproxalap in the U.S.
- Exclusive license to develop, manufacture, and commercialize outside the U.S.

Financial terms of license if option exercised:

- Upfront payment of $100 million less option fees
- $100 million milestone payment upon U.S. FDA approval in dry eye disease
- $200 million in additional regulatory and commercial milestones
- Profit and loss share (60% for AbbVie/40% for Aldeyra) from commercialization in U.S.
- Tiered royalties on net sales outside of U.S.

The option terminates on the earlier of (a) the 10th business day after the date on which Aldeyra received approval from the U.S. FDA of the NDA for reproxalap in dry eye disease and (b) the date that is 18 months after October 31, 2023. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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 U.S.†

†Company estimates and Am J Ophthalmol. 2014;157(4):799-806. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 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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News Release

Aldeyra Therapeutics Achieves Primary Endpoint in Phase 3 Dry Eye Disease Clinical Trial of Reproxalap

New Drug Application Resubmission Anticipated in 2024

Lexington, Mass., August 08, 2024 – 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 clinical trial of 0.25% reproxalap ophthalmic solution, an investigational new drug candidate, for the treatment of dry eye disease. Reproxalap was statistically superior to vehicle for the prespecified primary endpoint of ocular discomfort (P=0.004), a U.S. Food and Drug Administration (FDA)-accepted symptom of dry eye disease.

“To our knowledge, the results announced today represent the first positive Phase 3 clinical trial in a dry eye chamber with a symptom as a primary endpoint, and we believe that the results are supportive of the potential rapid clinical effect of reproxalap on reducing the ocular discomfort associated with dry eye disease,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

In the Phase 3 clinical trial, patients were administered vehicle (the drug product without the active ingredient) before and during exposure to a dry eye chamber in a manner that Aldeyra believes is consistent with the FDA’s dry eye disease draft guidance[1]. Qualifying patients were subsequently randomized to receive either reproxalap or vehicle before and during exposure to an additional dry eye chamber. Of the 132 patients randomized, 66 patients received reproxalap and 66 patients received vehicle. The primary endpoint was ocular discomfort, an FDA-accepted symptom of dry eye disease, from 80 to 100 minutes in the chamber. The dry eye chamber clinical trial was designed to satisfy the FDA’s New Drug Application (NDA) resubmission requirement, identified in the previously received complete response letter, of “at least one additional adequate and well-controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye.” Through the FDA Special Protocol Assessment process and additional comments, the FDA provided feedback on the clinical trial protocol and statistical plan.

1 www.fda.gov/media/144594/download

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 ocular redness. The potential NDA resubmission is anticipated in 2024. Based on FDA guidance, the resubmission NDA review period is expected to be six months.

There were no safety signals observed in the clinical trial, 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. No treatment-related discontinuations were reported. Reproxalap has now been studied in over 2,500 patients.

Conference Call & Webcast Information

Aldeyra will host a conference call at 9:00 a.m. ET today, August 8, 2024, to discuss the Phase 3 dry eye chamber trial results and the plan for resubmission of the NDA for reproxalap in dry eye disease. The dial-in numbers are (888) 596-4144 for domestic callers and (646) 968-2525 for international callers. The access code is 7321123. 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 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, 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.

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 2,500 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 Aldeyra's future expectations, plans, and prospects, including without limitation statements regarding: the goals, opportunity, and potential for reproxalap; 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 such NDA resubmission; 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, 2023, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/.

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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