
**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 1, 2026

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 1, 2026, Aldeyra Therapeutics, Inc. (“Aldeyra” or the “Company”) released an updated corporate overview presentation (the “Corporate Overview”) which, among other things, disclosed (i) standardized treatment estimates and confidence intervals for the primary endpoints of all proposed commercial dosing regimen efficacy clinical trials of reproxalap submitted to the New Drug Application for the treatment of dry eye disease and (ii) Aldeyra’s abbreviated interpretations of the U.S. Food & Drug Administration positions on the primary endpoints for the reproxalap clinical trials, as well as the Aldeyra positions on the primary endpoints.

A copy of the Corporate Overview 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 9.01.**Financial Statements and Exhibits.**

(d) Exhibits

	Exhibit No.	Description
99.1		Aldeyra Therapeutics, Inc. Corporate Overview dated May 1, 2026
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:

Name:

Title:

/s/ Todd C. Brady

Todd C. Brady, M.D., Ph.D.

Chief Executive Officer

Dated May 1, 2026



CORPORATE

Innovative Therapeutics for Immune-Mediated Diseases

May 2026

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 and results of ongoing or planned clinical trials; 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 potential FDA discussions and/or meetings, including Type A meetings; the outcome and timing of the FDA's acceptance, review, or approval of a potential NDA resubmission for reproxalap and the adequacy of the data included in such 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 outcome and timing of any clinical trials with ADX-2191; the outcome and timing of the FDA's acceptance, review, or approval of a potential NDA resubmission for ADX-2191 and the adequacy of the data expected to be included in such potential resubmitted NDA; the goals, opportunity and potential for reproxalap and its other product candidates; anticipated clinical or regulatory milestones for ADX-2191, ADX-248, 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-248, 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 (SEC). 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. Other than explicitly noted, the information in this presentation is provided only as of May 1, 2026, 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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A photograph of a woman with dark curly hair smiling and hugging a young girl with curly hair. They are both smiling broadly. The background is a bright, outdoor setting, possibly a beach or park.

ALDEYRA'S MISSION is to discover innovative therapies that improve the lives of patients who suffer from immune-mediated diseases.

OUR APPROACH is to develop pharmaceuticals that modulate protein systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity.



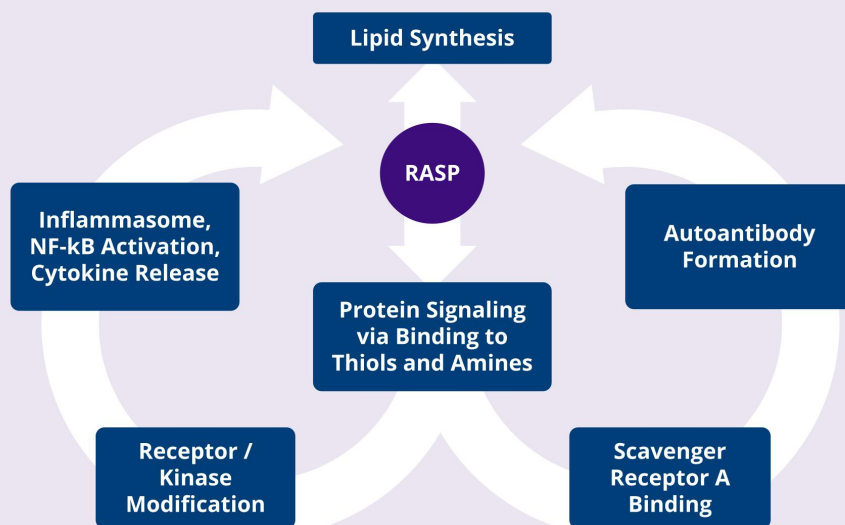
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Modulating RASP – A First-in-Class, Systems-Based Therapeutic Approach

RASP Represent a Novel, Potentially Broadly Applicable Pharmaceutical Target that Modulates Many Proteins at Once

- RASP are formed by oxidation of alcohols and other metabolic processes.
- RASP bind thiol (Michael addition) and amine (Schiff base) residues on proteins, leading to conformational and functional changes in certain proteins that **initiate pro-inflammatory signaling cascades**.
- RASP are also precursors of lipids and **may contribute to obesity and dyslipidemia**.



RASP=reactive aldehyde species

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RASP Modulation Represents a Novel Pharmacology

Traditional pharmacology targets specific proteins and is generally limited to two actions: on or off.



Activating or inhibiting specific proteins on a sustained basis, which rarely occurs in nature, may lead to toxicity and could limit activity.

VS.

RASP modulation may allow for control of protein *systems*, without turning any single protein on or off.



Systems-based pharmacology could potentially lead to broader-based activity with less toxicity associated with activation or inhibition of specific proteins.



RASP=reactive aldehyde species

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The Immune-Modulating Activity of Lead RASP Modulator Reproxalap is Supported by Peer-Reviewed Publications

AMERICAN JOURNAL OF OPHTHALMOLOGY
 Early Onset and Broad Activity of Reproxalap
 in a Randomized, Double-Masked,
 Vehicle-Controlled Phase 2b Trial in Dry Eye
 Disease

AMERICAN JOURNAL OF OPHTHALMOLOGY
 Clinically Relevant Activity of the Novel RASP
 Inhibitor Reproxalap in Allergic Conjunctivitis:
 The Phase 3 ALLEVIATE Trial

JOURNAL OF OCULAR PHARMACOLOGY AND THERAPEUTICS
 A Randomized Double-Masked Phase 2a Trial to Evaluate
 Activity and Safety of Topical Ocular Reproxalap,
 a Novel RASP Inhibitor, in Dry Eye Disease

Clinical Ophthalmology CLINICAL TRIAL REPORT
 The Phase 3 INVIGORATE Trial of Reproxalap in Patients
 with Seasonal Allergic Conjunctivitis

Clinical Ophthalmology ORIGINAL RESEARCH
 A Post-Acute Ocular Tolerability Comparison of
 Topical Reproxalap 0.25% and Lifitegrast 5% in
 Patients with Dry Eye Disease

Clinical Ophthalmology ORIGINAL RESEARCH
 Reproxalap Improves Signs and Symptoms of
 Allergic Conjunctivitis in an Allergen Chamber: A
 Real-World Model of Allergen Exposure

JOURNAL OF OCULAR PHARMACOLOGY AND THERAPEUTICS
 Randomized Phase 2 Trial of Reproxalap,
 a Novel Reactive Aldehyde Species Inhibitor,
 in Patients with Noninfectious Anterior Uveitis:
 Model for Corticosteroid Replacement

Ophthalmology and Therapy
 Reproxalap Activity and Estimation of Clinically
 Relevant Thresholds for Ocular Itching and Redness
 in a Randomized Allergic Conjunctivitis Field Trial

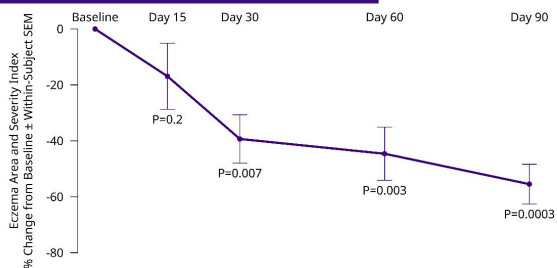


Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.
 FDA=U.S. Food & Drug Administration

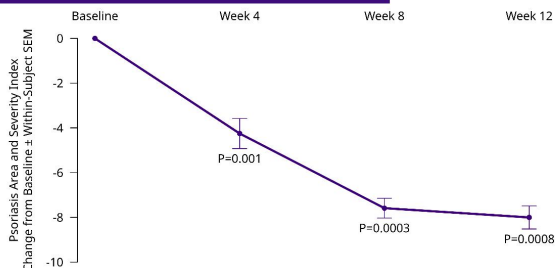
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ADX-629, a Signal-Finding Orally Administered RASP Modulator, Consistently Demonstrated Activity in Phase 2 Clinical Trials

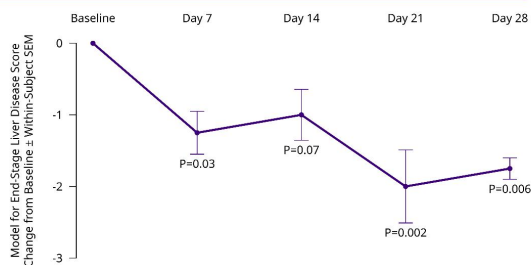
Autoimmune Disease: Atopic Dermatitis



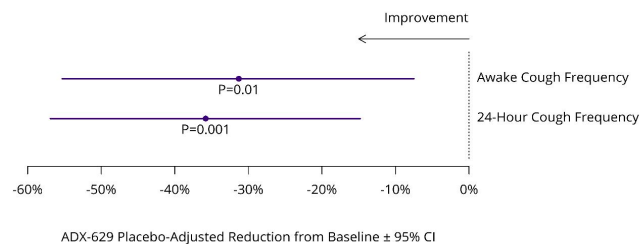
Autoimmune Disease: Psoriasis



Hepatic Inflammation: Alcohol-Associated Hepatitis



Idiopathic Inflammation: Chronic Cough

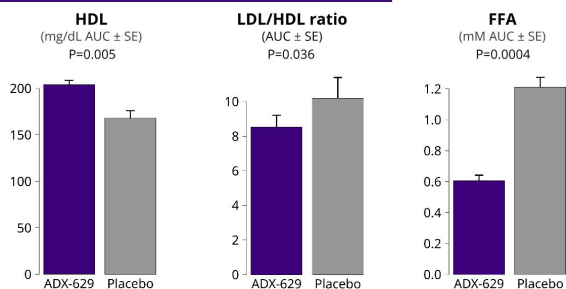


ADX-629 is an investigational drug candidate. RASP=reactive aldehyde species, SEM=standard error of the mean

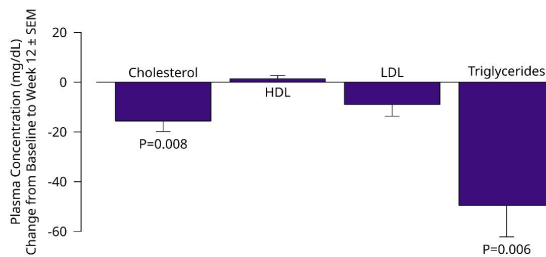


Statistically Significant Changes Observed in Lipid Profiles in Multiple Clinical Trials with RASP Modulator ADX-629

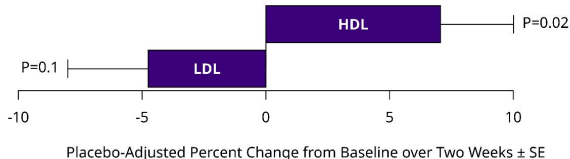
Phase 1 Clinical Trial



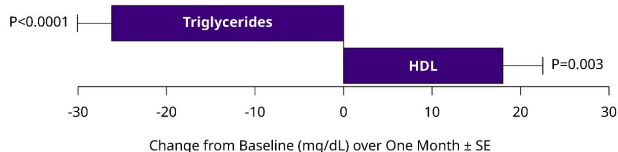
Phase 2 Psoriasis Clinical Trial



Phase 2 Chronic Cough Clinical Trial



Phase 2 Alcohol-Associated Hepatitis Clinical Trial

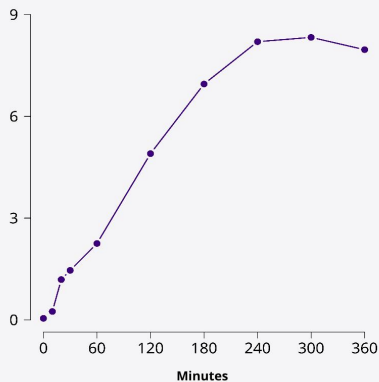


ADX-629 is an investigational drug candidate. AUC=area under the curve, FFA=free fatty acids, HDL=high-density lipoprotein, LDL=low-density lipoprotein, mM=millimolar, SE=linear model standard error, RASP=reactive aldehyde species, SEM=standard error of the mean

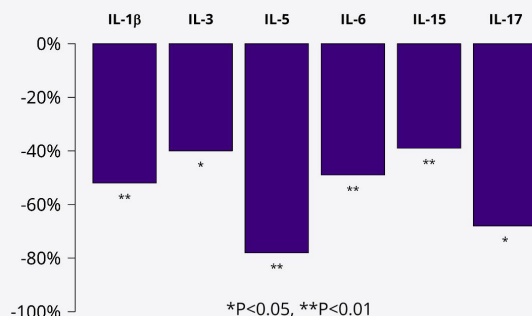


By Binding HNE, a Pro-Inflammatory RASP, ADX-248 Potentially Represents a New Orally Administered Therapy for the Treatment of Immune-Mediated Disease

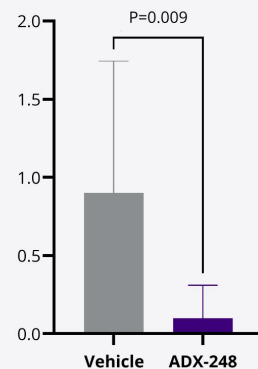
ADX-248 Binding to Pro-Inflammatory RASP HNE (HNE absorbance units)



Cytokine Reduction vs. Vehicle Control in LPS-Challenged Mice



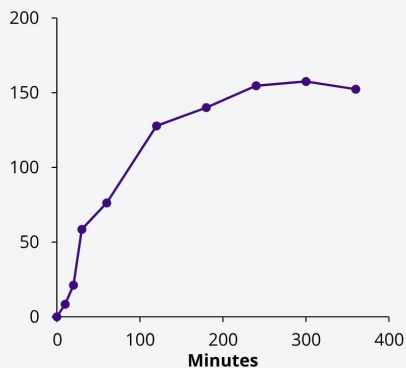
Epidermal Erosion Score (0-5) + SEM in Oxazolone Mouse Model of Atopic Dermatitis



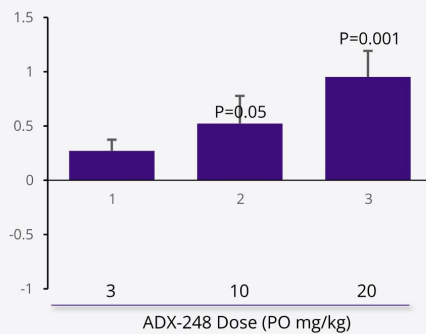
ADX-248 Increased Brain Dopamine and Improved Motor Function in a Preclinical Parkinson's Disease Model

MPTP Mouse Parkinson's Disease Model

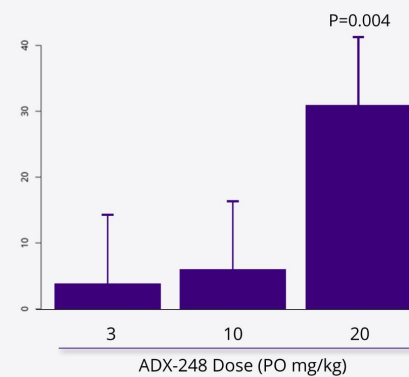
ADX-248 *In Vitro* Binding Neurotoxic RASP DOPAL (DOPAL absorbance units)



Brain Dopamine vs. Vehicle (ng dopamine / mg protein ± SE)



Rotarod Performance vs. Vehicle (time to fall, seconds ± SE)

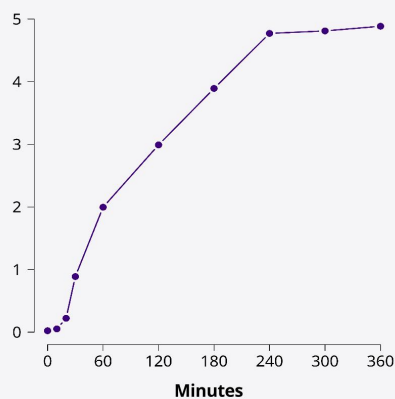


ADX-248 is an investigational drug candidate. DOPAL=3, 4-dihydroxyphenylacetaldehyde, MPTP=1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine, SE= mixed model for repeated measures standard error, PO=oral administration

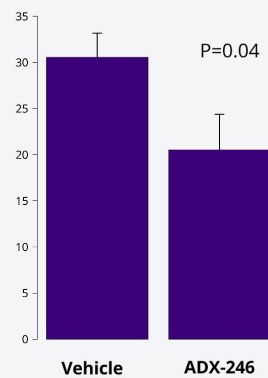


By Binding the RASP Retinaldehyde, ADX-246 Potentially Represents a New Intravitreally Administered Therapy for the Treatment of Dry Age-Related Macular Degeneration (Dry AMD)

ADX-246 Binding to RASP Retinaldehyde
(Retinaldehyde absorbance units)



Reduction in Toxic Retinaldehyde Metabolite A2E
(retinal picomoles + SEM) in *Abcr* Knockout Mouse
(Model of Dry AMD)



A2E is related to impairment in low-light vision,[†] one of the first symptoms of dry AMD.



[†]J Biol Chem, 297(3):101074, 2021. ADX-246 is an investigational drug candidate. A2E=bis-retinoid N-retinyl-N-retinylidene ethanolamine, RASP=reactive aldehyde species, SEM=standard error of the mean

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Reproxalap: A Novel RASP Modulator for the Treatment of Dry Eye Disease and Allergic Conjunctivitis

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 FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. FDA=U.S. Food & Drug Administration

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

The Complete Response Letter stated that “there is a lack of substantial evidence consisting of adequate and well-controlled investigations ... that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling” and that “the application has failed to demonstrate efficacy in adequate and well controlled studies in the treatment of signs and symptoms of dry eye disease.” The letter also stated that the “inconsistency of study results raises serious concerns about the reliability and meaningfulness of the positive findings” and that the “totality of evidence from the completed clinical trials does not support the effectiveness of the product.”

The FDA recommended that the reasons for failure in certain trials be explored, and that populations or certain conditions in which reproxalap may be effective be identified. The FDA did not recommend conducting additional trials or request submission of additional confirmatory evidence. As such, Aldeyra does not currently expect to pursue additional clinical trials.

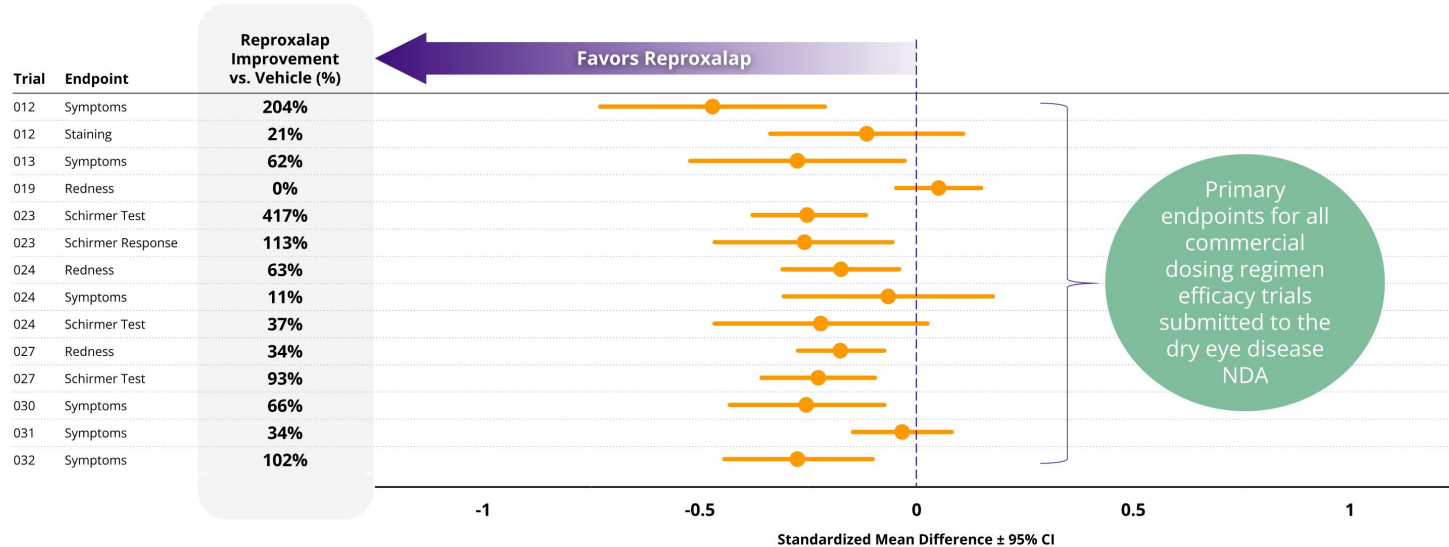
No manufacturing or safety issues were identified in the letter.

A Type A meeting to discuss the letter with the FDA is expected to be held in the second quarter of 2026.*

 *Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload, governmental shutdown, and other potential review issues. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; 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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Aldeyra Believes That the Totality of Evidence Indicates a Clear Pattern of Superiority of Reproxalap over the Vehicle Control



Vehicle is the drug product without reproxalap. Trials 012, 013, and 031 were field trials; other trials were single-day exposures (Day 1, Schirmer Test) followed by a dry eye chamber (Day 2, redness and symptoms). Trial 012 reflects the proposed commercial dosing regimen. For the plot, continuous outcomes from the prespecified MMRM differences are standardized by the pooled standard deviation across treatment groups. Schirmer response is analyzed as difference in response rates, standardized using a Bernoulli standard deviation. Treatment comparisons are reproxalap minus vehicle, except Schirmer score, which is vehicle minus reproxalap. The table represents unadjusted mean treatment comparisons as a percentage of vehicle mean. Trials=ADX-102-DED-xxx where xxx is the trial number, Symptoms=patient-reported dryness or discomfort, Staining=nasal fluorescein staining, Redness=investigator-assessed ocular redness, Schirmer=tear production score, Schirmer response= ≥ 10 mm response, CI=confidence interval, MMRM=mixed models for repeated measures, NDA=New Drug Application for reproxalap for the treatment of the signs and symptoms dry eye disease



The Majority of Reproxalap Dry Eye Trials Submitted to the Dry Eye Disease NDA Achieved Primary Endpoints Supporting Efficacy

TRIAL	PRIMARY ENDPOINT(S)	P<0.05	FDA POSITION	ALDEYRA POSITION
012	Symptoms Staining	✓	Co-primary not met	Supportive for symptoms
013	Symptoms	✓	Endpoint met	Endpoint met
019	Redness		Endpoint not met	Supportive for Schirmer Test (secondary P<0.0001), Schirmer Response (post-hoc P<0.0001)
023	Schirmer Test Schirmer Response	✓ ✓	Methodological issues	Endpoints met, methodological sensitivity testing supportive of outcome
024	Redness Symptoms Schirmer Test	✓	Redness endpoint met	Redness endpoint met; Symptoms and Schirmer Test numerically supportive
027	Redness Schirmer Test	✓ ✓	Redness met, Schirmer Test methodological issues	Both endpoints met, methodological sensitivity testing supportive of outcome for Schirmer Test
030	Symptoms	✓	Methodological issues	Endpoint met, methodological sensitivity testing supportive of outcome
031	Symptoms		Not statistically significant	Results numerically favored symptoms
032	Symptoms	✓	Endpoint met	Endpoint met

Five of the nine
efficacy trials submitted to the NDA achieved all primary endpoints, and the P values for 9 of 14 endpoints were less than 0.05.

The table presents the primary endpoints from all proposed commercial dosing regimen efficacy trials of reproxalap that were submitted to the dry eye disease NDA. FDA position is Aldeyra's abbreviated interpretation of FDA review. Trials=ADX-102-DED-xxx where xxx is the trial number, Symptoms=patient-reported dryness (Trials 012 and 013) or discomfort (Trials 030, 031, and 032), Staining=nasal region fluorescein staining, Redness=investigator-assessed ocular redness, Schirmer Test=tear production score, Schirmer Response= ≥ 10 mm response, FDA=US Food and Drug Administration, NDA=New Drug Application for reproxalap for the treatment of the signs and symptoms dry eye disease



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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.
- Option terminates on the 10th business day after Aldeyra receives approval from the U.S. FDA of the NDA for reproxalap in dry eye disease

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 AbbVie logo is displayed in a dark blue, lowercase sans-serif font.

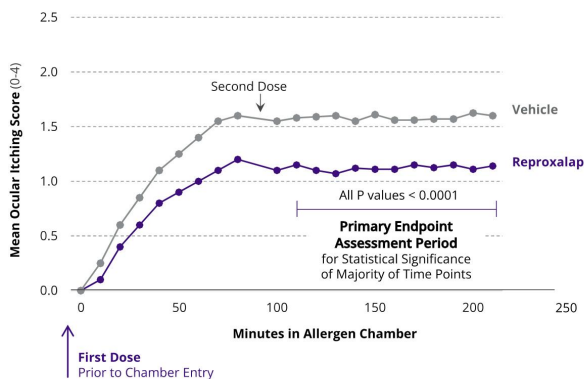
Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.
FDA=U.S. Food & Drug Administration, NDA=New Drug Application

The Aldeyra logo is displayed in a dark blue, lowercase sans-serif font.

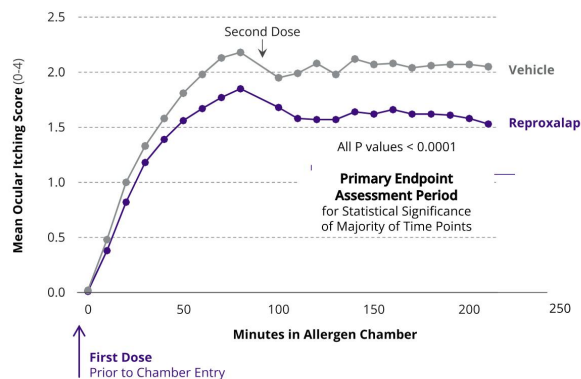
Aldeyra Believes Efficacy Requirements Have Been Met for Potential NDA Submission of Reproxalap for Allergic Conjunctivitis[†]

Phase 3 INVIGORATE Allergen Chamber Trials Primary Endpoint of Patient-Reported Ocular Itching

INVIGORATE



INVIGORATE-2



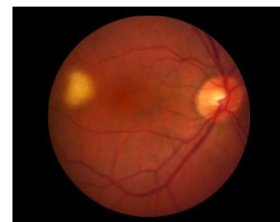
[†]NDA submission requirements depend, in part, on regulatory feedback. Topical ocular reproxalap is an investigational drug candidate that has not been approved by the FDA; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. NDA=New Drug Application



ADX-2191: A Platform Approach for the Treatment of Rare Retinal Diseases

ADX-2191 Has the Potential to be the First Approved Drug for Primary Vitreoretinal Lymphoma (PVRL), a Rare but Serious Retinal Cancer

- **A rare, aggressive, high-grade cancer**, PVRL arises in the vitreous and retina.
- Approximately **200-600 new cases** of PVRL are diagnosed in the United States per year.
- **Median survival is less than 5 years** for newly diagnosed patients.
- **No approved treatments** are currently available, though compounded intraocular methotrexate injection represents current standard of care.
- **U.S. FDA Orphan Drug Designation** has been granted.
- **Special Protocol Assessment agreement** has been received from the FDA, and a single trial will be sufficient to support NDA resubmission.



Small (top) and large (bottom) subretinal infiltrates in patients with primary vitreoretinal lymphoma



Sources: Aldeyra internal estimates and data on file; Primary Vitreoretinal Lymphoma by D. J. Wilson on AAO EyeWiki; M. Sagoo, Survey of Ophthalmology (2014); Grimm et. al., Annals of Oncology (2007). ADX-2191 (methotrexate injection, USP) is an investigational drug candidate. FDA=U.S. Food & Drug Administration, NDA=New Drug Application

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Phase 3 Clinical Trial Design of ADX-2191 in Patients with PVRL

Design

Double-masked, 1:1 randomized, parallel-group, multicenter trial in up to 20 patients with biopsy-proven PVRL

Dosing Regimen

Cohort A: Monthly injections

Cohort B: Twice-weekly injections, followed by weekly injections

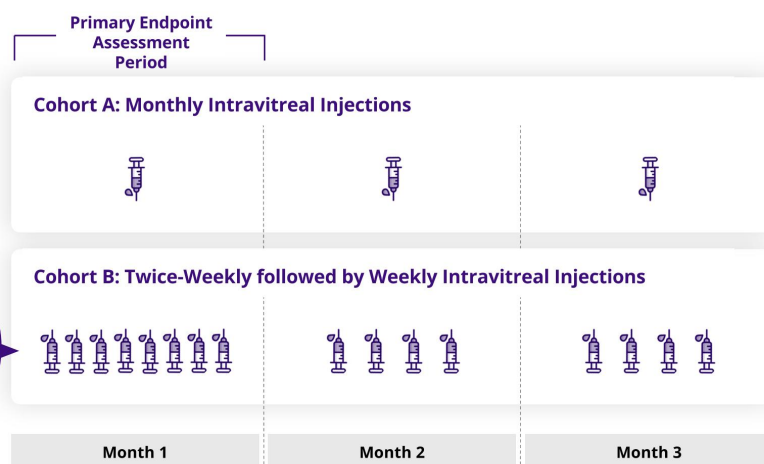
Primary Endpoint

Clearance of cancer cells over four weeks

Secondary Endpoints

1. Change in visual acuity over one month
2. Time to cancer cell clearance over 12 weeks

On average,
5
injections are
required for
cancer cell
clearance.*



Phase 3 clinical trial initiation expected H1 2026; results expected in 2026[‡]



[†]Br J Haematol, 194: 92–100, 2021; Cancer Sci. 107:1458-1464, 2016. ADX-2191 (methotrexate injection, USP) is an investigational drug candidate.[‡]The clinical trial design may change based on regulatory feedback, and 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. ADX-2191 (methotrexate injection, USP) is an investigational drug candidate.

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ADX-2191 has the potential to be the first approved drug for retinitis pigmentosa, a clinical group of rare genetic eye diseases.

Retinitis pigmentosa refers to a group of inherited retinal diseases characterized by cell death and loss of vision.



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- Retinitis pigmentosa **affects more than 1 million people** worldwide. Mutations leading to rhodopsin misfolding account for approximately 10% of cases.
- Preclinical evidence suggests that methotrexate may be active in rhodopsin misfolding mutations by facilitating degradation of mutated rhodopsin.
- **U.S. FDA Orphan Drug Designation** has been granted.



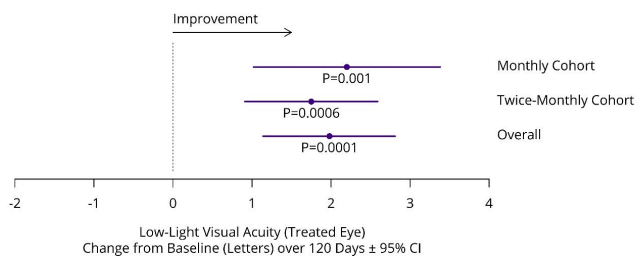
Preclinical electroretinographic evidence in a P23H rhodopsin mutation mouse model of retinitis pigmentosa **suggests that methotrexate improves retinal function.**

ADX-2191 (methotrexate injection, USP) is an investigational drug candidate. Sources: Aldeyra internal estimates; FASEB J. 2020 Aug;34(8):10146-10167. MTX=methotrexate, PBS=phosphate-buffered saline

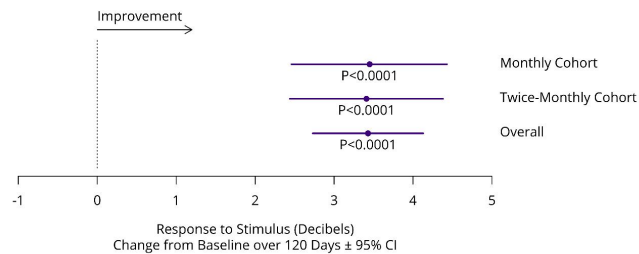
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In the Phase 2 Retinitis Pigmentosa Clinical Trial of ADX-2191, Retinal Sensitivity Improved from Baseline

Visual Acuity in Dim Light



Dark Adapted Sensitivity to Green Light



Phase 2 clinical trial was performed in eight retinitis pigmentosa patients with rhodopsin misfolding mutations: four patients received monthly injections for three months; four patients received twice-monthly injections for three months. Dark adapted chromatic perimetry used to assess sensitivity to green light stimuli. ADX-2191 (methotrexate injection, USP) is an investigational drug candidate.



Planned Phase 2/3 Clinical Trial of ADX-2191 in Retinitis Pigmentosa

Design	Randomized, double-masked, clinical trial
Dosing	High-dose (400 µg) and low-dose (200 µg) dose administered monthly for 12 months vs sham injections
Size	45 retinitis pigmentosa patients with rhodopsin mutations, randomized 1:1:1 <ul style="list-style-type: none">• High-dose (400 µg)• Low-dose (200 µg)• Sham injection
Primary Endpoint	Peripheral vision sensitivity to green (rod-mediated) light under dark-adapted conditions
Other Endpoints	Best-corrected and low-light visual acuity, safety

Clinical trial initiation expected in H1 2026*



*The clinical trial design may change based on regulatory feedback, and 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. ADX-2191 (methotrexate injection, USP) is an investigational drug candidate.

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Corporate Information

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Bill Cavanagh
Vice President, Clinical Operations



Adam Lazorchak, Ph.D.
Director, Translational Sciences/
Non-clinical Development



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 ¹Acquired by Xanthus/Antisoma. ²Acquired by Schwarz/UCB. ³Acquired by Hesperion AG. ⁴Acquired by Shire. ⁵Acquired by Genzyme.

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Clinical and Regulatory Milestones



Reproxalap



ADX-248



ADX-246



ADX-2191



Dry Eye Disease (Reproxalap)

Type A meeting with the FDA is expected to be held in the second quarter of 2026[†]



Atopic Dermatitis (ADX-248)

Phase 2 clinical trial initiation expected in H1 2026[†]



Obesity/Hypertriglyceridemia (ADX-248)

Investigational New Drug application expected to be submitted in 2026



Dry Age-Related Macular Degeneration/Geographic Atrophy (ADX-246)

Investigational New Drug application expected to be submitted in 2026



Primary Vitreoretinal Lymphoma (ADX-2191)

Phase 3 clinical trial initiation expected in H1 2026[†]



Retinitis Pigmentosa (ADX-2191)

Phase 2/3 clinical trial initiation expected in H1 2026[†]

[†]Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload, governmental shutdown, and other potential review issues. ^{††}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. PDUFA=Prescription Drug User Fee Act



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