# 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): February 13, 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.**

As previously announced by Aldeyra Therapeutics, Inc. (the "Company"), on February 13, 2024, the Company's President and Chief Executive Officer will participate virtually in a fireside chat at the Oppenheimer 34th Annual Healthcare Life Sciences Conference during which he will be discussing the clinical and regulatory status of Aldeyra's product candidates. A copy of the presentation which may be referenced during the conversation is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the slide presentation is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report.

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. Presentation dated February 13, 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 February 13, 2024

Exhibit 99.1


aldeyra
CORPORATE
Innovative Therapeutics
for Immune-Mediated Diseases
February 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: the outcome and expected timing of discussions with the FDA 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 and discussions, 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 February 13, 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.

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**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 immunological 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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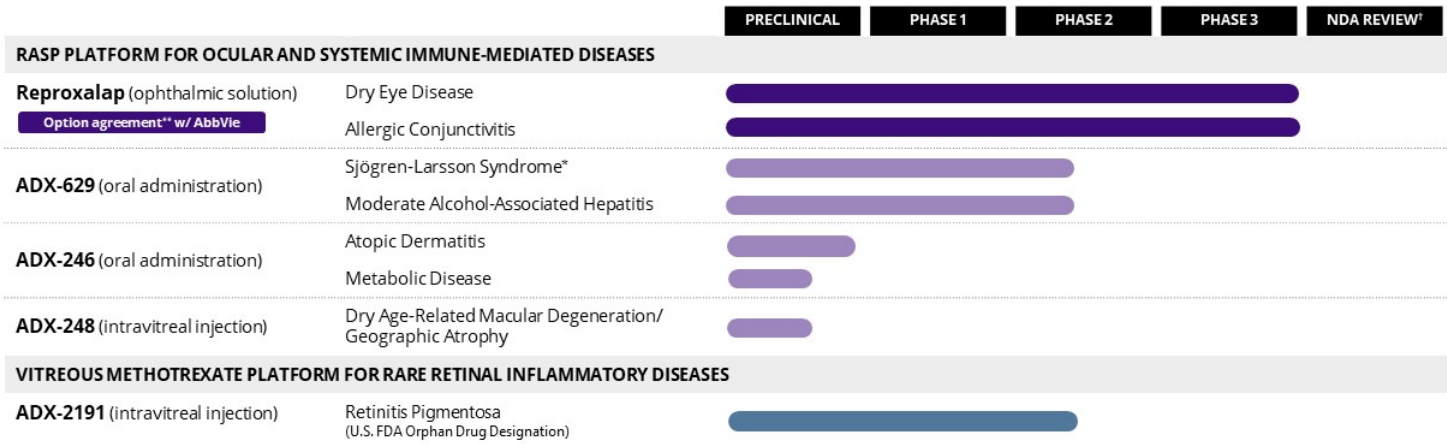
# Aldeyra Is a Well-Capitalized Biotechnology Company with a Broad Immunology Pipeline




**As of 9/30/2023, cash and cash equivalents were $143.3M, which Aldeyra believes will be sufficient to fund the Company into late 2025.‡**

†Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. ‡Company guidance as of November 28, 2023; includes clinical trial costs associated with a potential NDA resubmission; the initial commercialization and launch plans for reproxalap; and continued early and late-stage development of our product candidates in ocular and systemic immune-mediated diseases. Guidance does not include any potential licensing or product revenue associated with reproxalap. NDA = New Drug Application. *Investigator sponsored **Option agreement outlined on slide 12.

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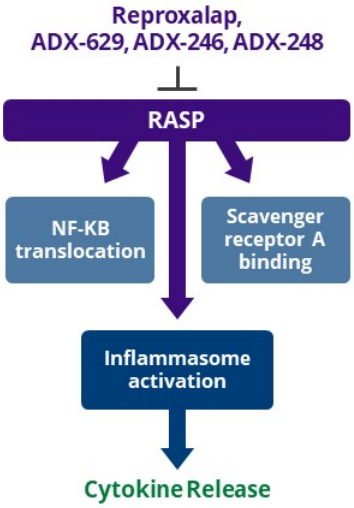
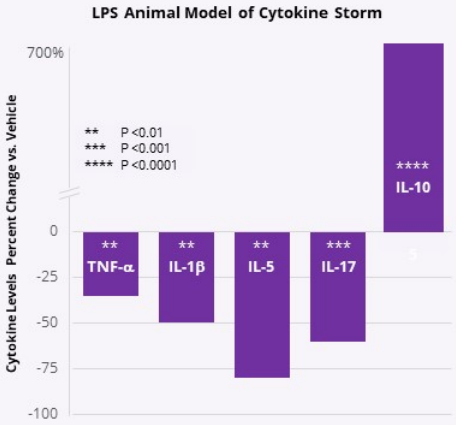
# Modulating RASP – A First-in-Class, Systems-Based Therapeutic Approach

# Aldeyra is the Leading Developer of RASP Modulators: A Novel Approach Supported by Late-Stage Trials




## Preclinical Broad-Based Cytokine Reduction

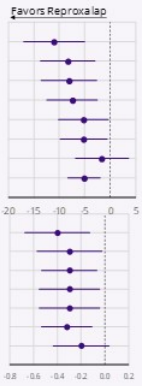



## Broad-Based Symptom Reduction

**RENEW-Part 1 Phase 3 Dry Eye Disease Trial**

Symptom Treatment Difference[1] (Reproxalap-Vehicle) Weeks 2 -12

| 0-100 Ocular Symptom Scales | P-value |
|---|---|
| VAS: Ocular Dryness (Co-Primary) | 0.0004 |
| VAS: Eye Discomfort | 0.0025 |
| VAS: Photophobia | 0.0041 |
| VAS: Foreign Body Sensation | 0.0035 |
| VAS: Itching | 0.0346 |
| VAS: Pain | 0.0268 |
| VAS: Burning/Stinging | NS |
| **OSDI** (Total) | 0.0020 |
| **0-4 & 0-5 Ocular Symptom Scales** | |
| OD4S: Grittiness | 0.0025 |
| OD4S: Dryness | 0.0134 |
| OD4S: Ocular Discomfort | 0.0268 |
| OD4S: Burning | 0.0306 |
| OD4S: Stinging | 0.0239 |
| CAC Ocular Itching Scale | 0.0034 |
| Ocular Discomfort Scale | NS |




[1]Treatment difference of induction-maintenance dosing, defined as the difference between the changes from baseline for the evaluated drug minus vehicle (least squares mean difference ± 95% confidence interval). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170). Sources: Cullen, et al. The Small Molecule Aldehyde Trap NS2 Exhibits Potent Anti-Inflammatory Activity in Three Murine Models of Inflammation [abstract]. In: The Journal of Allergy and Clinical Immunology. Volume 135, Issue 2, AB384, Feb 2015; Reproxalap RENEW-Part 1 clinical trial results. RASP = reactive aldehyde species. LPS = lipopolysaccharide. VAS = visual analog scale. OSDI = Ocular Surface Disease Index. NS = not significant. OD4SQ = Ocular Discomfort & 4-Symptom Questionnaire. CAC = conjunctival allergen challenge.

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# The Activity of Lead RASP Modulator Reproxalap is Supported by Marquee Peer-Reviewed Publications


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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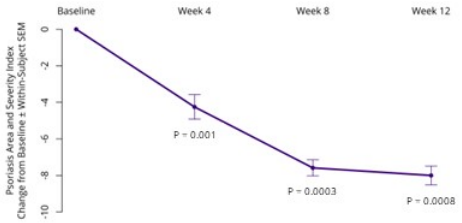
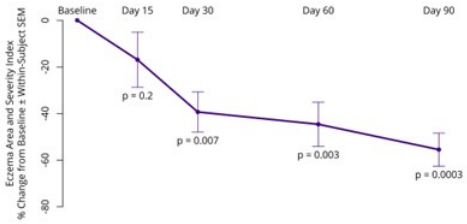
# ADX-629, a First-in-Class Orally Administered RASP Modulator, Has Demonstrated Activity in Phase 2 Clinical Trials

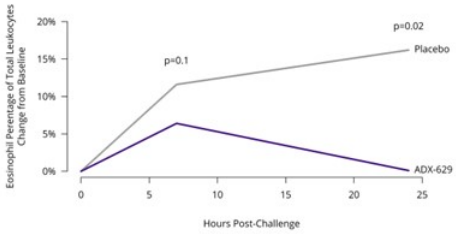
### Autoimmune Disease: Psoriasis



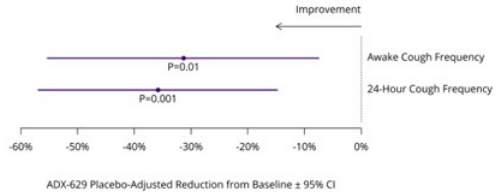

### Autoimmune Disease: Atopic Dermatitis




### Allergic Inflammation: Asthma




### Idiopathic Inflammation: Chronic Cough




ADX-629 is an investigational drug candidate. SEM = standard error of measurement.

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# ADX-629 Data Suggest Potential for Next-Generation Investigational RASP Modulators ADX-246 and ADX-248

## ADX-246

**Oral Administration**

... designed to treat immune-mediated systemic diseases thought to be caused or exacerbated by pro-inflammatory RASP.

Pre-clinical studies of ADX-246 demonstrated high affinity for RASP and activity following systemic administration in animal models of sepsis, hepatitis, and atopic dermatitis.

## ADX-248

**Intravitreal Injection**

... designed to reduce inflammation and toxic metabolite formation associated with geographic atrophy, a severe form of macular degeneration.

Preclinical studies of ADX-248 demonstrated high affinity for binding retinaldehyde, a key RASP involved in retinal inflammation and the formation of toxic metabolites that accumulate in the retina.

ADX-629 is an investigational drug candidate.

# The RASP Platform is Validated by Reproxalap, a Novel Potential Therapeutic Approach in Dry Eye Disease

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

**Rapid symptom improvement**

**Broad symptomatic activity**

**Acute increase in tear production and 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. NDA = New Drug Application. 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 Received a Complete Response Letter from the FDA for the Reproxalap NDA for the Treatment of Dry Eye Disease

- An additional trial is required to demonstrate activity in symptoms.
- Based on Special Protocol Assessment (SPA) feedback received from the FDA in December 2023, Aldeyra has amended the proposed clinical trial protocol and statistical analysis plan.
- Proposed clinical trial top-line results and potential NDA resubmission are expected in the second half of 2024, pending clinical trial results, feedback from ongoing FDA discussions, and other factors.†

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. †Regulatory review and discussion 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 the availability of clinical research facilities and staffing, the ability to recruit patients, and the number of patients in the trial.

# 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:

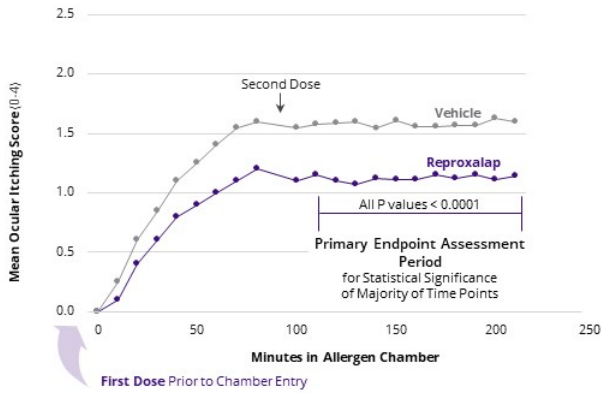
- Upfront payment of $100 million less option fees
- $100 million milestone payment upon U.S. FDA approval in dry eye disease
- $200 million in additional regulatory and commercial milestones
- Profit and loss share (60% for AbbVie/40% for Aldeyra) from commercialization in U.S.
- Tiered royalties on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

Source: Aldeyra Therapeutics, Inc.'s Current Reports on Form 8-K filed with the Securities and Exchange Commission on November 1, 2023, and December 21, 2023, respectively. 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 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

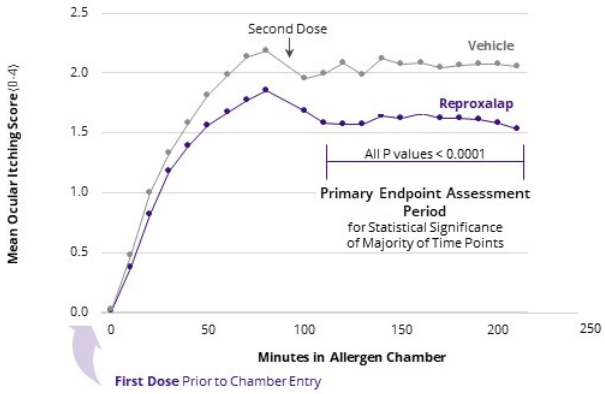
# Aldeyra Believes Efficacy Requirements Have Been Met for Potential NDA Submission of Reproxalap for Allergic Conjunctivitis†

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

### INVIGORATE




### INVIGORATE-2




†NDA submission requirements depend, in part, on clinical results, enrollment, and regulatory feedback. Source: INVIGORATE and INVIGORATE-2 clinical trial results. 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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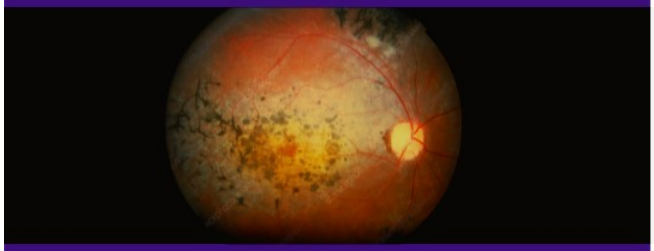
# ADX-2191: A Novel Approach for the Treatment of Retinitis Pigmentosa

# 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.



- Retinitis pigmentosa **affects more than 1 million people** worldwide. Mutations leading to rhodopsin misfolding account for approximately one-third 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** received August 2021


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

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

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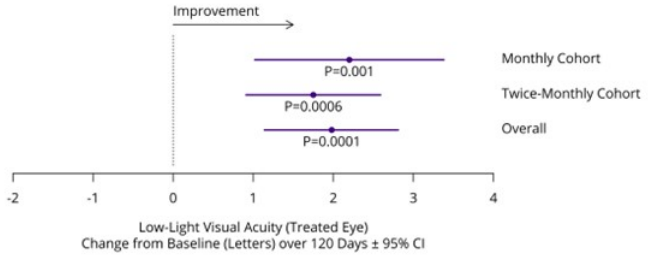
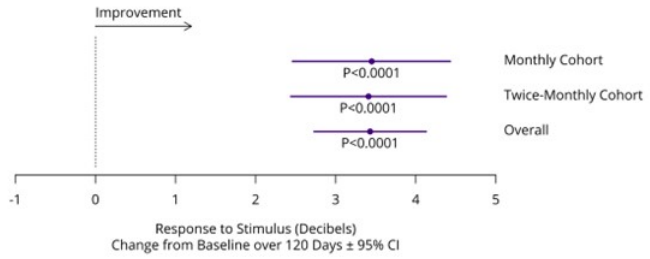
# In the Phase 2 Retinitis Pigmentosa Clinical Trial, Retinal Sensitivity Improved from Baseline

## 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.

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# Corporate Information

# Experienced Management Team and Board of Directors

## MANAGEMENT TEAM

**Todd Brady, M.D., Ph.D.**
President, CEO & Director

**Bruce Greenberg, C.P.A.**
SVP of Finance and Interim Chief Financial Officer

**Stephen Machatha, Ph.D.**
Chief Development Officer

## BOARD OF DIRECTORS

| | |
|---|---|
| **Richard Douglas, Ph.D.** Chairman | Former SVP Corporate Development at Genzyme |
| **Ben Bronstein, M.D.** | Former CEO Peptimmune[6] |
| **Marty Joyce** | Former CFO of Serono USA |
| **Nancy Miller-Rich** | Former SVP BD&L and Commercial Strategy at Merck |
| **Gary Phillips, M.D.** | CBO Anaveon AG |
| **Neal Walker, D.O.** | Chairman Aclaris Therapeutics |
| **Todd Brady, M.D., Ph.D.** | CEO Aldeyra Therapeutics |

1. Acquired by Xanthus/Antisoma. 2. Acquired by Schwarz/UCB. 3. Acquired by Ligand. 4. Acquired by Merck. 5. Acquired by Alexion. 6. Acquired by Genzyme.

# Clinical and Regulatory Milestones


†Regulatory review and discussion 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 the availability of clinical research facilities and staffing, the ability to recruit patients, and the number of patients in the trial. *Investigator sponsored.

- [x] **Allergic Conjunctivitis**
  Positive Phase 3 INVIGORATE 2 trial top-line results announced
- [ ] **Dry Eye Disease**
  Proposed clinical trial top-line results and potential NDA resubmission expected in second half of 2024, pending clinical trial results, feedback from ongoing FDA discussions, and other factors†‡
- [x] **Sjögren-Larsson Syndrome**
  Phase 2 clinical trial top-line results announced*
- [ ] **Moderate Alcohol-Associated Hepatitis**
  Open-label Phase 2 clinical trial results expected H2 2024‡
- [ ] **Atopic Dermatitis**
  Phase 1 clinical trial initiation expected in H1 2024‡
- [x] **Metabolic Disease**
  Pre-clinical program initiated
- [ ] **Dry Age-Related Macular Degeneration/Geographic Atrophy**
  IND expected to be submitted in 2024
- [ ] **Retinitis Pigmentosa**
  Type C Meeting with FDA expected in first quarter of 2024 to discuss pivotal clinical testing†

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