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): January 7, 2021

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 January 7, 2021, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") regarding the top-line symptom and sign results from the run-in cohort of its Phase 3 TRANQUILITY Trial in dry eye disease. The Company is holding a conference call on January 7, 2021. 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.

On January 7, 2021, the Company issued a press release regarding the top-line symptom and sign results from the run-in cohort of its Phase 3 TRANQUILITY Trial in dry eye disease. The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K 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 January 7, 2021.
99.2	Aldeyra Therapeutics, Inc. Press Release dated January 7, 2021.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

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

Dated: January 7, 2021

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed
Name: Joshua Reed
Title: Chief Financial Officer

January 7, 2021

DATA RELEASE

Initial Symptom and Sign Results From Run-In Cohort of Phase 3 TRANQUILITY Trial in Dry Eye Disease

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, research and development plans or expectations, political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures and other responses to it, that may affect Aldeyra's business or the global economy, the structure, timing and success of Aldeyra's planned or pending clinical trials, 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. As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete Aldeyra's clinical trials may be delayed. 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," "target," "design," "estimate," "predict," "potential," "plan" or similar expressions and the negatives of those terms.

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, clinical and regulatory plans or expectations for Aldeyra's product candidates 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 smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale trials or the remainder of a clinical trial, inconsistent expectations regarding FDA acceptance and review of the company's filings and submitted data sets, and Aldeyra's continuing 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, 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, 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 January 7, 2021**, 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.

Initial Results From Run-In Cohort of Phase 3 TRANQUILITY Trial Support First-Line Potential of Reproxalap in Dry Eye Disease

- Statistical significance achieved for both sign and symptoms in dry eye chamber:*
  - Reproxalap demonstrated statistically significant improvement over vehicle in ocular redness (p=0.03), an FDA-approvable objective sign.
  - Reproxalap demonstrated statistically significant improvement over vehicle for the two assessed clinical symptoms: VAS Ocular Dryness (p=0.001) and Ocular Discomfort Score (p<0.0001).
- Acute improvements in ocular symptoms and objective sign within minutes of reproxalap administration in a dry eye chamber.
- 24-hour environmental results supportive of reproxalap's rapid and broad efficacy, with consistent directional improvements over vehicle across symptoms and Schirmer's test, and statistical significance vs. vehicle achieved in four of eight assessed outcome measurements.
- The main cohort of TRANQUILITY is expected to begin enrollment in February 2021, following completion of tear RASP analysis from the run-in cohort and confirmation of endpoints and patient numbers.

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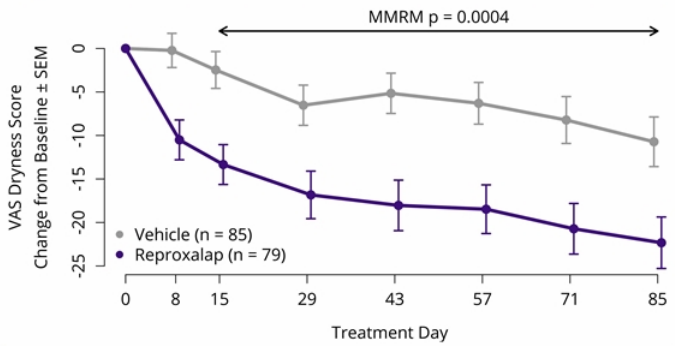
*Based on Mixed Model Repeated Measures (MMRM p values shown above). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials. Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0).
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
RASP = Reactive Aldehyde Species

Reproxalap Demonstrated Rapid, Broad, and Durable Symptom Improvement Over 12 Weeks of Chronic Therapy in Prior Trials

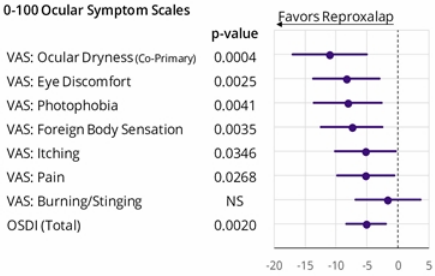
RENEW-Part 1 Phase 3 Trial
(Induction-Maintenance Dosing)



Reproxalap demonstrated statistically significant symptom improvements over vehicle as early as one week after treatment initiation.

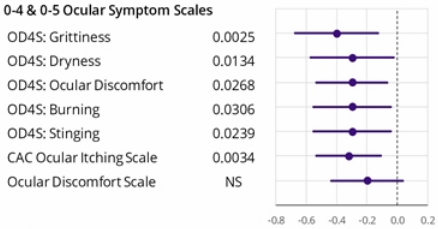
Symptom Treatment Difference‡ (Reproxalap-Vehicle) Over Weeks 2 to 12

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

‡Treatment Difference of induction-maintenance dosing, defined as the difference between the changes from baseline for the evaluated drug vs. vehicle (LS Mean Difference ± 95% CI). Ocular Dryness Score co-primary endpoint assessed in pre-specified patient population having an OD4S dryness baseline score of ≥ 3 (N=170). Topical ocular reproxalap has been studied in over 1,100 patients with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Induction-Maintenance dosing defined as QID dosing (4x daily) for weeks 1-4 followed by BID dosing (2x daily) for weeks 5-8.
Source: Reproxalap RENEW-Part 1 clinical trial results and TRANQUILITY Run-In Cohort initial results.

VAS = Visual Analog Scale
OD4S = Ocular Discomfort & 4-Symptom
CAC = Conjunctival Allergen Challenge
MMRM = Mixed Effect Model Repeated Measures

TRANQUILITY Run-In Cohort Evaluated Acute Effects of Reproxalap in Dry Eye Disease Patients

Run-In cohort objective:

- Evaluate efficacy of reproxalap compared to vehicle in dry eye disease after single and multiple doses, and after exposure to a dry eye chamber.
- Power and confirm primary and secondary endpoints for the main cohort of the Phase 3 TRANQUILITY clinical trial.

Initial Results Available Today

Day 1 (24 hour)
- Dry Eye Symptoms
- Schirmer's Test

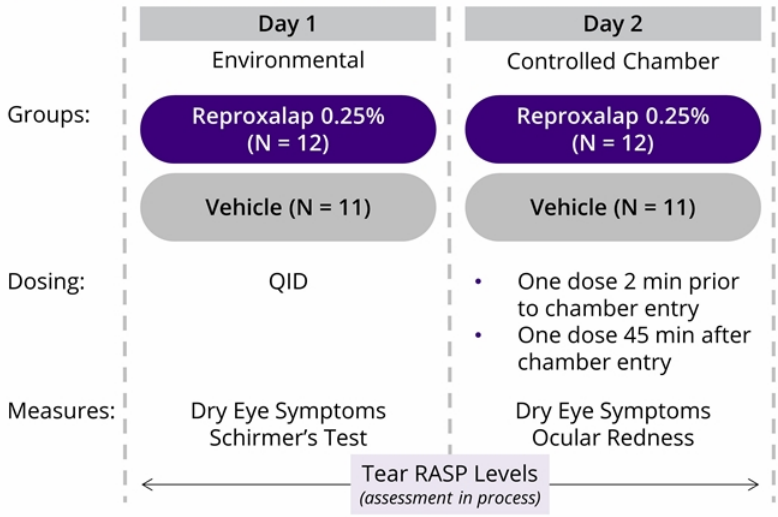
Day 2 (Chamber)
- Dry Eye Symptoms
- Ocular Redness

Assessment Currently In Process

Day 1 – Day 2
- Tear RASP Levels

Main cohort expected to begin enrollment in February 2021, following completion of tear RASP analysis from run-in cohort and confirmation of endpoints and patient numbers.

TRANQUILITY Run-In Cohort Design



QID = Four times daily

Reproxalap Demonstrated Rapid And Broad Improvements After Only One Day of Treatment in TRANQUILITY Run-In Cohort

TRANQUILITY Run-In Cohort Day 1 (24 Hours) Results:*

Dry Eye Assessment (Scale) After Environmental Dosing	Change From Baseline		P-Value
	Reproxalap (N = 12)	Vehicle (N = 11)	
VAS Dryness (0-100)	-26	+2	**0.003**
OD4S: Discomfort (0-5)	-0.7	+0.4	**0.003**
OD4S: Dryness (0-5)	-1.2	+0.1	**0.006**
OD4S: Grittiness (0-5)	-1.1	+0.1	**0.006**
OD4S: Burn (0-5)	-0.1	+0.8	0.07
OD4S: Sting (0-5)	-0.1	+0.4	0.23
Ocular Discomfort Scale (0-4)	-0.7	+0.4	0.07
Schirmer's Test (mm)*	+3.4	+1.3	0.30

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*Day 1 Schirmer's Test results based on improvement after a single dose; all other Day 1 assessments performed over 24 hours of QID dosing. Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
OD4S = Ocular Discomfort & 4-Symptom Questionnaire
QID = Four times daily

The Dry Eye Chamber:
A Demanding Real-World Drug Assessment of Dry Eye Disease

- Challenge-model trials utilizing a controlled chamber are an FDA accepted design for pivotal endpoints.*
- Dry eye chambers control relative humidity, temperature, airflow, and visual tasking in order to stress the ocular surface.
  - Chambers simulate a “bad day” scenario in the life of a dry eye disease sufferer.
- Trial designs utilizing chambers are able to confirm the utility of drugs with rapid onset of action during an acute ocular surface challenge.

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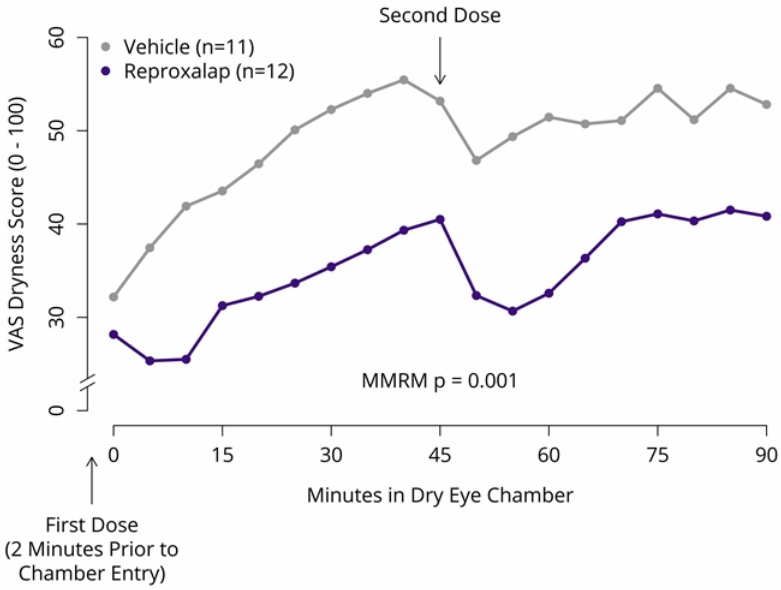
*FDA published “Dry Eye: Developing Drugs for Treatment” draft guidance; December 2020.

Reproxalap Demonstrated Acute and Durable Improvements in Ocular Dryness in TRANQUILITY Run-In Dry Eye Chamber

TRANQUILITY Run-In Cohort Day 2 Results: Ocular Dryness Score (VAS) in Dry Eye Chamber

- Drug effect over vehicle observed upon entry and sustained throughout duration of exposure.
- Therapeutic activity demonstrated after first and second doses, representing near-immediate (within minutes) and statistically significant symptom relief vs. vehicle.
- Consistent and statistically significant improvements over vehicle observed across all symptoms evaluated in the chamber.



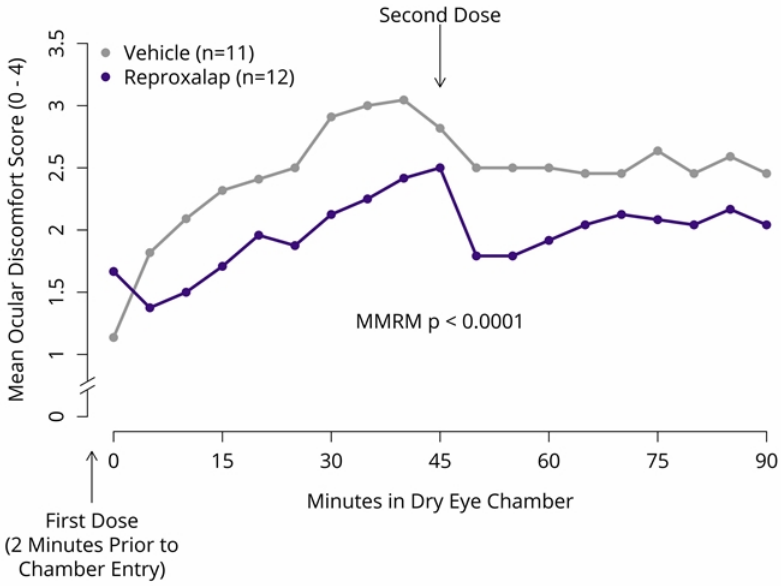
Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

Reproxalap Demonstrated Acute and Durable Improvements in Ocular Discomfort in TRANQUILITY Run-In Dry Eye Chamber

TRANQUILITY Run-In Cohort Day 2 Results: Ocular Discomfort Scale (0-4) in Dry Eye Chamber

- Drug effect over vehicle observed upon entry and sustained throughout duration of exposure.
- Therapeutic activity demonstrated after first and second doses, representing near-immediate (within minutes) and statistically significant symptom relief vs. vehicle.
- Consistent and statistically significant improvements over vehicle observed across all symptoms evaluated in the chamber.



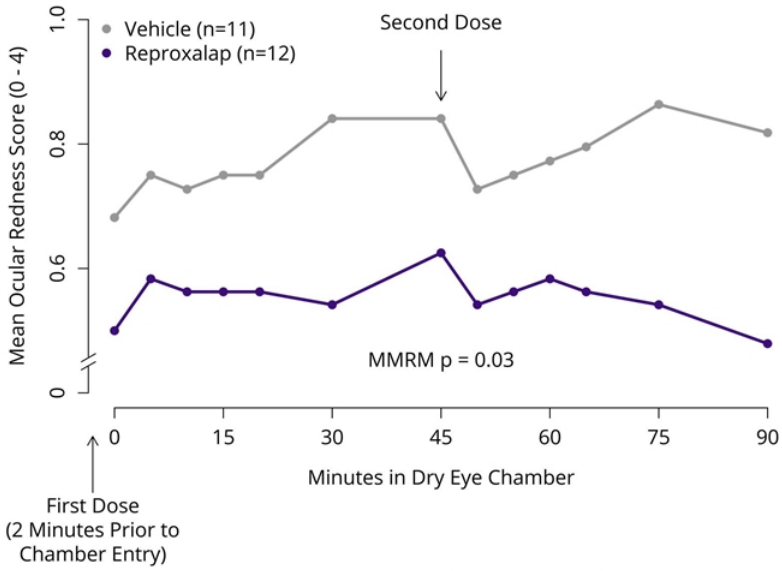
Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

Reproxalap Demonstrated Acute and Durable Improvements in Ocular Redness in TRANQUILITY Run-In Dry Eye Chamber

TRANQUILITY Run-In Cohort Day 2 Results: Ocular Redness Score (0-4) in Dry Eye Chamber

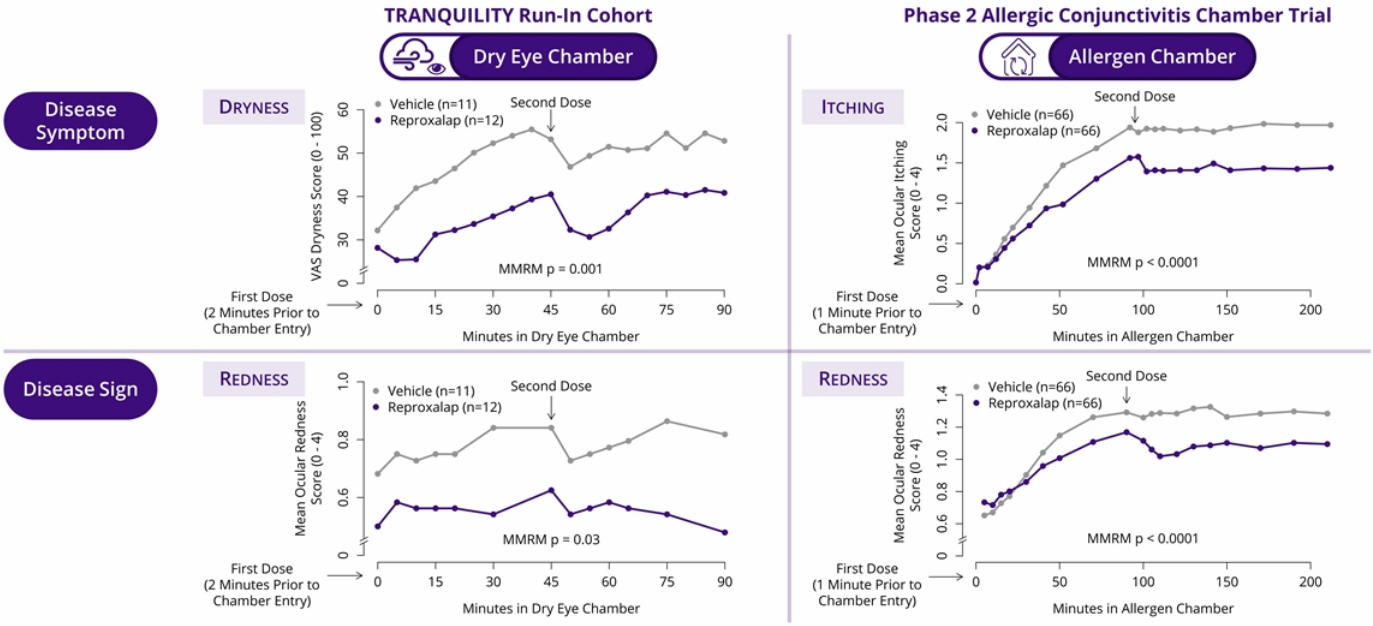
- Drug effect over vehicle observed upon entry and sustained throughout duration of exposure.
- Therapeutic activity demonstrated after first and second dose, representing near-immediate (within minutes) and statistically significant objective sign relief vs. vehicle.
- Ocular redness is an FDA-approvable objective sign endpoint for dry eye disease.*



*Currently FDA approved dry eye products have utilized Schirmer's Test, corneal staining, and conjunctival hyperemia (redness) as objective sign measures.
Mixed effect model of repeated measures (MMRM) for change from baseline (Time 0). Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

Reproxalap Has Demonstrated Consistent Symptom and Sign Results Across Two Chamber Challenge Models in Ocular Surface Diseases



Topical ocular reproxalap has been studied in over 1,100 patients thus far with no observed safety concerns; mild instillation site irritation is the most commonly reported adverse event in clinical trials.
Source: TRANQUILITY Run-In Cohort initial results; Phase 2 Allergen Chamber clinical trial – reproxalap 0.25% (ClinicalTrials.gov #NCT03709121)

VAS = Visual Analog Scale
MMRM = Mixed Model Repeated Measures

TRANQUILITY Main Cohort Clinical Trial Design

- Main cohort trial design, endpoints, and patient numbers to be confirmed following completion of tear RASP analysis from the run-in cohort.
- TRANQUILITY main cohort design options:

Trial Design Option:

Challenge-Model

Duration:	**Two days**
Size:	**~200 patients total***
Primary endpoint:	Objective DED Sign
Secondary endpoints:	Additional DED Sign and DED Symptoms
Design:	Multi-center randomized, double-masked, parallel design, vehicle-controlled clinical trial

Trial Design Option:

Challenge-Model + Environmental Exposure

Duration:	**Four weeks**
Size:	**~200 patients total***
Primary endpoint:	Objective DED Sign
Secondary endpoints:	Additional DED Sign and DED Symptoms
Design:	Multi-center randomized, double-masked, parallel design, vehicle-controlled clinical trial

Main cohort expected to begin enrollment in February 2021.

*Pending final powering based on final run-in cohort results.

Upcoming Expected Reproxalap Development Milestones*

- Reproxalap dry eye disease
  Phase 3 TRANQUILITY main cohort enrollment initiation February 2021
- Reproxalap dry eye disease
  Phase 3 TRANQUILITY-2 initiation Q1 2021
- Reproxalap allergic conjunctivitis
  Phase 3 INVIGORATE study top-line results H1 2021

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*The timing of clinical trial initiation and completion depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, the ability to recruit patients, and regulatory feedback.

Exhibit 99.2

Aldeyra Therapeutics Announces Positive Top-Line Symptom and Sign Results from Run-In Cohort of Phase 3 TRANQUILITY Trial in Dry Eye Disease

- Statistical Significance of Reproxalap Over Vehicle Achieved for Ocular Redness, an FDA-Approvable Sign, and Clinical Symptoms of Ocular Dryness and Discomfort
- Acute Improvement in Ocular Redness and Symptom Scores Demonstrated Within Minutes of Reproxalap Administration in Dry Eye Chamber
- Main Cohort of TRANQUILITY Expected to Begin Enrollment in February 2021, Following Completion of Tear RASP Analysis and Finalization of Trial Design
- Management to Host Conference Call at 8:00 a.m. ET Today

LEXINGTON, Mass., January 7, 2021 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced positive top-line symptom, redness, and Schirmer's test results from the run-in cohort of the Phase 3 TRANQUILITY clinical trial in patients with dry eye disease.

The double-masked, single-center, parallel-group run-in cohort enrolled 23 patients: 12 patients were randomized to receive 0.25% reproxalap ophthalmic solution and 11 patients were randomized to receive vehicle ophthalmic solution. Patients received four doses one day prior to and two doses on the day of exposure to a 90-minute dry eye chamber with minimal humidity, high airflow, and forced visual tasking.

Over all time points in aggregate in the dry eye chamber, reproxalap was observed to be statistically superior to vehicle for the two assessed symptoms, visual analog scale (VAS) ocular dryness score ($p = 0.001$) and ocular discomfort score ($p < 0.0001$) in the run-in cohort of TRANQUILITY. Consistent with previously announced allergen chamber Phase 2 clinical trial results, reproxalap demonstrated statistically significant improvement over vehicle ($p = 0.03$) in ocular redness, an objective sign of dry eye disease. Improvement in ocular symptoms and redness occurred within minutes after reproxalap dosing. Following acute dosing on the day prior to the dry eye chamber, Schirmer test scores were directionally in favor of reproxalap over vehicle, and reproxalap was statistically superior to vehicle in improvement in VAS dryness score ($p = 0.003$), ocular discomfort 4-symptom questionnaire (OD4SQ) dryness score ($p = 0.006$), OD4SQ grittiness score ($p = 0.006$), and OD4SQ discomfort score ($p = 0.003$). Consistent with clinical experience in over 1,100 patients, no adverse findings on safety assessments were observed, and reproxalap was well-tolerated.

“The symptom improvement observed in the run-in cohort of TRANQUILITY announced today support the first-line potential use of reproxalap in dry eye disease, and represent the first results from an ophthalmic solution for chronic use that demonstrate activity acutely following drug administration,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “The activity of reproxalap in reducing ocular redness, initially demonstrated in the allergen chamber Phase 2 clinical trial, was also observed in the dry eye chamber run-in results of TRANQUILITY, and we look forward to initiating enrollment of the main cohort.”

Among many patients and physicians, current dry eye disease therapies are considered inadequate. Discontinuation rates for lifitegrast and cyclosporine, which currently comprise standard of care, exceed 60% within 12 months of initiation of therapy, in part due to delayed onset of effect.[1]

“The potential for patients to experience acute symptomatic relief and observe rapid improvement in ocular redness after the initiation of therapy represents a new possible paradigm in dry eye disease treatment and could offer significant clinical advantage over existing therapies, which often require weeks of drug administration before patients experience even moderate improvement,” stated Victor Perez, M.D., Professor of Ophthalmology at Duke University School of Medicine and a member of Aldeyra’s Anterior Segment Scientific Advisory Board.

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1 White DE, Zhao Y, Ogundele A, et al. Real-World Treatment Patterns of Cyclosporine Ophthalmic Emulsion and Lifitegrast Ophthalmic Solution Among Patients with Dry Eye. Clin Ophthalmol. 2019;13:2285-2292.

The main cohort of TRANQUILITY is expected to begin enrollment in February 2021, following completion of tear RASP analysis from the run-in cohort and confirmation of endpoints and number of subjects. Results from TRANQUILITY are expected in the second half of 2021. A second Phase 3 clinical trial, TRANQUILITY-2, is expected to initiate in the first quarter of 2021.

Conference Call Information

Aldeyra will host a conference call to discuss this announcement today, Thursday, January 7, 2021, at 8:00 a.m. ET. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID is 7076648. A live webcast of the conference call will also be available on the Investor Relations section of the Aldeyra Therapeutics website at https://ir.aldeyra.com. Presentation slides will be available on the investor relations page approximately 30 minutes prior to the start of the conference call and webcast.

After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

About Reproxalap

Reproxalap is a novel small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap is currently in Phase 3 clinical development as a 0.25% ophthalmic solution for the treatment of dry eye disease and allergic conjunctivitis, two ocular inflammatory diseases that often occur together in the same patient.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect 34 million or more adults in the United States.[2] The disease is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, diminished quality of life, and in severe cases, permanent vision impairment. Among many physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate and often requires weeks or months to demonstrate activity. In patients with dry eye disease, pro-inflammatory RASP may contribute to ocular inflammation and changes in tear lipid composition. By diminishing RASP levels, Aldeyra's lead RASP inhibitor reproxalap represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases. Two of the company's lead investigational compounds, reproxalap and ADX-629, target RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease and result in cytokine release via activation of a broad array of inflammatory factors, including NF-κB, inflammasomes, and Scavenger Receptor A. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The company's clinical pipeline also includes ADX-2191, a dihydrofolate reductase inhibitor in Phase 3 testing for proliferative vitreoretinopathy, and ADX-1612, a chaperome inhibitor in development for COVID-19 and ovarian cancer. For more information, visit https://www.aldeyra.com/ and follow us on LinkedIn, Facebook, and Twitter.

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2 Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. Am J Ophthalmol. 2014;157(4):799-806. doi:10.1016/j.ajo.2013.12.023.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the initial clinical results from the run-in cohort of the Phase 3 TRANQUILITY Trial and expectations regarding the main cohort of TRANQUILITY and the TRANQUILITY-2 Trial. 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," "potential," "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, and other factors that could delay the initiation 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; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; 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; the risk that the results from smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale trials or the remainder of a clinical trial; 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) 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 revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures, that may affect Aldeyra's business or the global economy; 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 limited sales and

marketing infrastructure; 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; 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, 2019 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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, 2020, expected to be filed with the SEC in the first quarter of 2021.

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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