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): June 8, 2022 (June 7, 2022)

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 5.07. Submission of Matters to a Vote of Security Holders.

At the 2022 annual meeting of stockholders (the "Annual Meeting") of Aldeyra Therapeutics, Inc. (the "Company") held on June 7, 2022, the following proposals were submitted to the stockholders of the Company:

Proposal 1: The election of three directors to serve as Class II directors until the Company's 2025 annual meeting of stockholders or until their successors are duly elected and qualified or until their earlier death, resignation or removal.

Proposal 2: The ratification of the appointment of BDO USA, LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2022.

Proposal 3: The approval, on a non-binding, advisory basis, of the compensation of the Company's named executive officers.

For more information about the foregoing proposals, see the Company's definitive proxy statement on Schedule 14A filed with the United States Securities and Exchange Commission on April 25, 2022 (the "Proxy Statement"). Of the 58,301,491 shares of the Company's common stock entitled to vote at the Annual Meeting, 37,611,008 shares, or approximately 64.5%, were represented at the meeting in person or by proxy, constituting a quorum. The number of votes cast for, against or withheld, as well as abstentions and broker non-votes, if applicable, in respect of each such proposal is set forth below:

Proposal 1: Election of Directors.

The Company's stockholders elected the following directors to serve as Class II directors until the 2025 annual meeting of stockholders or until their successors are duly elected and qualified or until their earlier death, resignation or removal. The votes regarding the election of the directors were as follows:

Director	Votes For	Votes Withheld	Broker Non-Votes
Richard H. Douglas, Ph.D.	11,068,901	15,420,242	11,121,865
Gary M. Phillips, M.D.	25,892,681	596,462	11,121,865
Neal S. Walker, D.O.	26,032,048	457,095	11,121,865

Proposal 2: Ratification of Appointment of BDO USA, LLP.

The Company's stockholders ratified the appointment of BDO USA, LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2022. The votes regarding this proposal were as follows:

Votes For	Votes Against	Votes Abstaining
37,529,239	52,835	28,934

Proposal 3: Advisory Vote on Executive Compensation.

The Company's stockholders approved, on a non-binding, advisory basis, the compensation of the Company's named executive officers as described in the Proxy Statement. The votes regarding this proposal were as follows:

Votes For	Votes Against	Votes Abstaining	Broker Non-Votes
23,243,909	3,179,900	65,334	11,121,865

Item 7.01. Regulation FD Disclosure.

As reported under Item 8.01 of this Current Report on Form 8-K, on June 8, 2022, the Company issued a press release (the "Press Release") announcing the achievement of both primary endpoints of the Phase 3 TRANQUILITY-2 clinical trial of 0.25% reproxalap ophthalmic solution (reproxalap) and the Company's plans to submit a new drug application ("NDA") with the U.S. Food and Drug Administration ("FDA"). The Company is holding a conference call regarding the Phase 3 clinical trial results on June 8, 2022. A copy of the supplemental presentation which will be referenced during the conference call 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 June 8, 2022, the Company announced in the Press Release the achievement of both primary endpoints of the Phase 3 TRANQUILITY-2 clinical trial of 0.25% reproxalap ophthalmic solution (reproxalap) and the Company's plans to submit a NDA with the FDA. 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 June 8, 2022.
99.2	Aldeyra Therapeutics, Inc. Press Release dated June 8, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: June 8, 2022


aldeyra
June 8, 2022
Top-Line Results from the Phase 3 TRANQUILITY-2 Trial in Dry Eye Disease
NASDAQ: ALDX
©Aldeyra Therapeutics, Inc. 2022

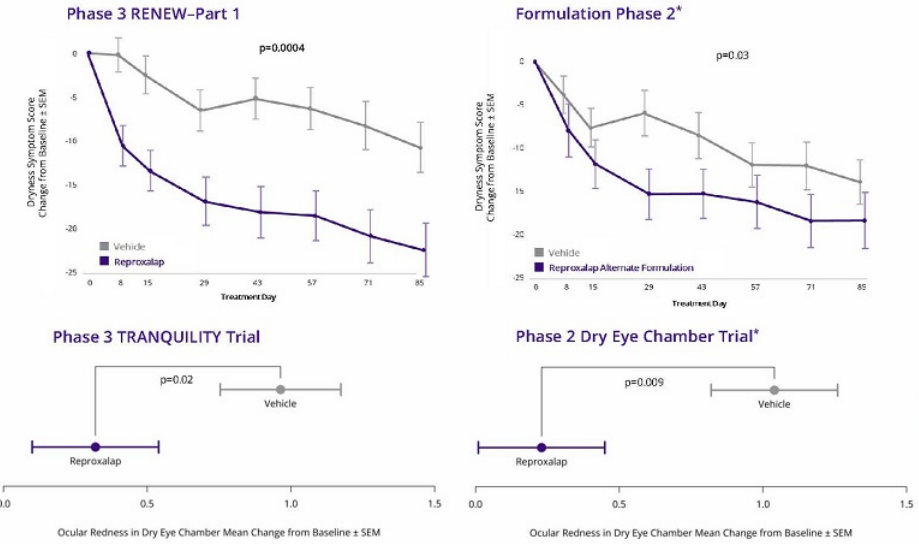
Disclaimers and Forward-Looking Statements

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, expectations regarding the timing and results of the expected Type B Pre-NDA meeting, including the FDA's acceptance of Aldeyra's post-hoc review of data and agreement with Aldeyra's methods of analyzing data, research, development and regulatory plans or expectations, political, economic, legal, social and health risks, including the COVID-19 pandemic and related 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 investigational new drugs (including reproxalap), 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, 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, enrollment, 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 June 8, 2022**, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

Aldeyra Previously Achieved Statistical Significance in Two Symptom and Two Sign Pivotal Trials†



Symptoms

Aldeyra intends to submit two previously completed 12-week adequate and well-controlled **symptom trials** that prespecified patient-reported ocular dryness score as a primary endpoint or a co-primary endpoint.

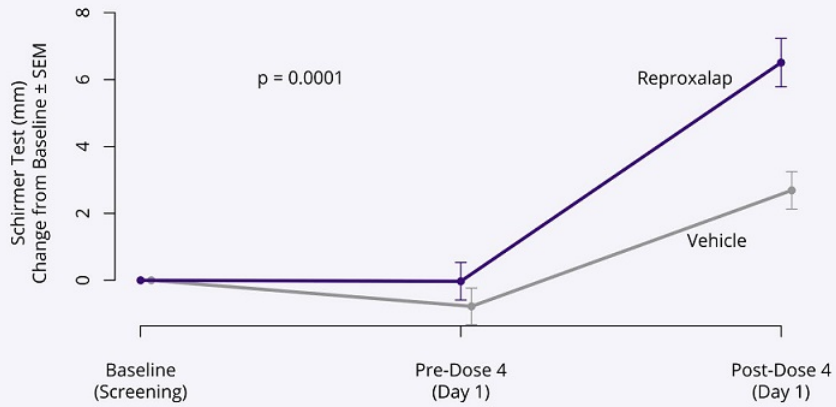
Signs

Aldeyra intends to submit two previously completed adequate and well-controlled dry eye chamber trials that prespecified **ocular redness** as a primary endpoint#. Ocular redness is an FDA-recognized, objective sign of dry eye disease.

†NDA submission requirements depend, in part, on clinical results and regulatory feedback. *Adequate and well-controlled Phase 2 or Phase 3 clinical trials can be submitted as pivotal. #Phase 2 and TRANQUILITY redness results derived from draft re-analysis using an automated assessment. **Source**: Clinical trial results on file. **SEM** = standard error of the mean. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

As a Secondary Endpoint, Schirmer Test Achieved in TRANQUILITY and Clinical Relevance Confirmed with Post-Hoc Responder Analysis

Schirmer Test



≥10 mm Schirmer Test Responder Analysis

	Reproxalap (n=153)	**Vehicle** (n=153)
≥10 mm increase in tear production post-Dose 4 on Day 1	31%	15%
Odds ratio (95% confidence interval)‡	2.6 (1.7, 4.1)	
p-value‡ versus vehicle	< 0.0001	

Graph horizontal axis values offset for clarity; graph p value derived from mixed effect model of repeated measures of change from baseline over pre- and post-Dose 4 scores on Day 1.
‡Generalized estimating equation analysis of change from baseline over pre- and post-Dose 4 scores on Day 1. **SEM** = standard error of the mean. **mm** = millimeter. **Source**: Phase 3 TRANQUILITY clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

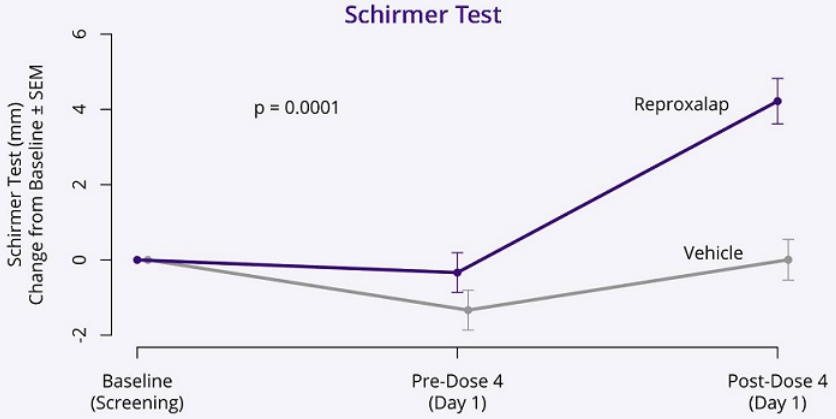
To Allow for Potential Submission of Two Dry Eye Disease Signs, Schirmer Test Designated as Primary Endpoint of TRANQUILITY-2

Design	Multi-center, randomized, double-masked, parallel group, vehicle-controlled
Dosing	0.25% reproxalap or vehicle Day 1: four doses Day 2: one dose before dry eye chamber, one dose in chamber
Size	361 patients
Primary Endpoints	Schirmer test on Day 1 pre/post Dose 4 Schirmer test responders (≥10 mm)
Secondary Endpoints	Ocular redness over 90 minutes in dry eye chamber Dry eye disease symptoms

Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

In TRANQUILITY-2, Both Primary Endpoints Were Achieved

Schirmer Test



≥10 mm Schirmer Test Responder Analysis

	Reproxalap (n=181)	**Vehicle** (n=180)
≥10 mm increase in tear production post-Dose 4 on Day 1	25%	8%
Odds ratio (95% confidence interval)‡	2.6 (1.7, 4.1)	
p-value‡ versus vehicle	< 0.0001	

Consistent with prior trials, no clinically significant safety signals were observed.

Graph horizontal axis values offset for clarity; graph p value derived from mixed effect model of repeated measures of change from baseline over pre- and post-Dose 4 scores on Day 1.
‡ Generalized estimating equation analysis of change from baseline over pre- and post-Dose 4 scores on Day 1. **SEM** = standard error of the mean. **mm** = millimeter. **Source**: Phase 3 TRANQUILITY-2 clinical trial results on file. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

The TRANQUILITY-2 Results May Allow for the Most Comprehensive Dry Eye Disease NDA Submitted to Date†

- Aldeyra believes that the clinical efficacy requirements for dry eye disease NDA submission have been met.
- We intend to submit an NDA covering symptoms (ocular dryness) and three sign endpoints (ocular redness, Schirmer test, and Schirmer test responder proportions) across five adequate and well-controlled clinical trials.
- Submitted clinical data is expected to encompass acute (single-day dosing, dry eye chamber) and chronic (12-week) assessments, offering unparalleled analysis of rapid and sustained activity across a combination of challenge and field-based assessments.
- If approved, reproxalap has the potential to be the first dry eye disease drug with at least two labeled objective signs.
- A Type B Pre-NDA meeting is expected to be held with the FDA in the third quarter of 2022, followed by a potential NDA submission.
- Enrollment is substantially complete in a crossover dry eye chamber trial that is intended to be adequate and well-controlled, and, pending the results, is expected to be submitted to the NDA as a supportive trial.

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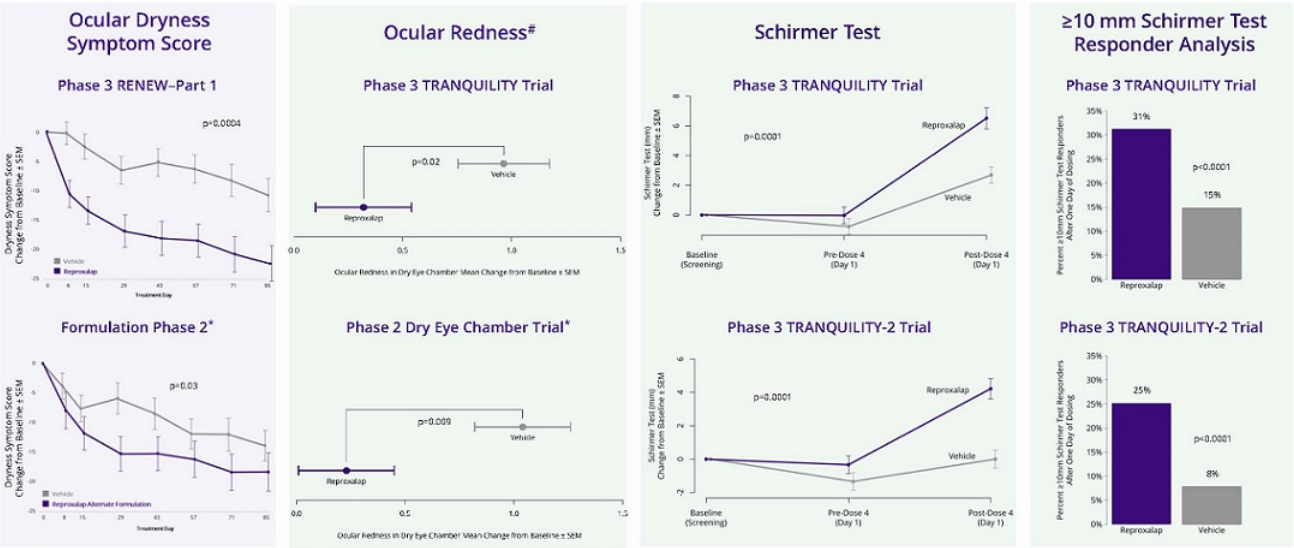
†NDA submission requirements depend, in part, on clinical results and regulatory feedback. The NDA submission is expected to include a combination of prespecified, post-hoc, primary, secondary, multiplicity-adjusted, and nominal p-value endpoints. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials

Aldeyra Intends to Submit Symptom and Three Sign Endpoints for Satisfaction of Dry Eye Disease NDA Efficacy Requirements†



†NDA submission requirements depend, in part, on clinical results and regulatory feedback. The NDA submission is expected to include a combination of prespecified, post-hoc, primary, secondary, multiplicity-adjusted, and nominal p-value endpoints. *Adequate and well-controlled Phase 2 or Phase 3 clinical trials can be submitted as pivotal. #Phase 2 and TRANQUILITY redness results derived from draft re-analysis of redness results using an automated assessment. **Source**: Clinical trial results on file. **SEM** = standard error of the mean. Topical ocular reproxalap is an investigational drug candidate that has been studied in more than 1,700 patients with no observed safety concerns; mild and transient instillation site discomfort is the most commonly reported adverse event in clinical trials.

Exhibit 99.2

Aldeyra Therapeutics Achieves Primary Endpoint in Phase 3 TRANQUILITY-2 Trial in Dry Eye Disease and Intends to Submit New Drug Application for Symptoms and Three Sign Endpoints of Dry Eye Disease

- ***Reproxalap Statistically Superior to Vehicle for Both Prespecified Primary Endpoints of Schirmer Test (p=0.0001) and ≥10 mm Schirmer Test Responder Proportions (p<0.0001)***
- ***TRANQUILITY-2 Results May Allow for the Most Comprehensive Dry Eye Disease New Drug Application (NDA) Submission to Date***
- ***Pending Pre-NDA Meeting with the U.S. Food and Drug Administration (FDA), Clinical Efficacy Trials of Reproxalap Believed to Be Complete***
- ***Company to Host Conference Call at 8:00 a.m. ET Today***

LEXINGTON, Mass.--(BUSINESS WIRE)--June 8, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced the achievement of the primary endpoint in the Phase 3 TRANQUILITY-2 clinical trial (TRANQUILITY-2) of reproxalap, an investigational new drug candidate, for the treatment of dry eye disease. Reproxalap was statistically superior to vehicle for each of the two prespecified primary endpoints, Schirmer test (p=0.0001) and ≥10 mm Schirmer test responder proportions (p<0.0001) after a single day of dosing. The Schirmer test, a measure of ocular tear production, is the dry eye disease objective sign most commonly utilized for drug approval.

“Schirmer test is an accepted method for measuring tear production and has been used in clinical studies for over 20 years,” said Cathleen McCabe, M.D., a dry eye disease specialist for The Eye Associates in Sarasota, Florida and Chief Medical Officer at Eye Health America™. “I am extremely encouraged about the Schirmer test results and the other clinical sign endpoint data produced by reproxalap, highlighting the broad therapeutic benefit this therapy may bring to patients suffering from dry eye disease.”

Pending discussions with the FDA, Aldeyra intends to submit an NDA with ocular dryness symptom score, ocular redness, Schirmer test, and ≥10 mm Schirmer test responder analysis, encompassing results across five adequate and well-controlled completed clinical trials. The submission could represent the most comprehensive NDA submission in dry eye disease to date and allows for the potential of reproxalap to be the first dry eye disease drug approved with symptoms and at least two labeled objective signs. The clinical package is expected to offer unparalleled breadth across acute trials over one to two days of dosing and chronic trials over 12 weeks of dosing, as well as a combination of challenge and field-based assessments.

“Many of my dry eye disease patients complain that current treatments take too long to work, prolonging symptoms and negatively affecting quality of life,” said Jacob R. Lang, O.D., F.A.A.O., a dry eye disease specialist for Associated Eye Care in St. Paul, Minnesota. “Based on its rapid symptomatic control demonstrated across multiple clinical trials, reproxalap has the potential to be not only an important treatment option but a first-line therapy for dry eye disease.”

A Type B Pre-NDA meeting is expected to be held with the FDA in the third quarter of 2022, followed by a potential NDA submission, pending enrollment in the ongoing 12-month safety trial, and results from a dry eye chamber crossover trial. Enrollment of the crossover dry eye disease trial is substantially complete, and results are expected in the third quarter of 2022. Pending the results, the crossover trial is intended to be submitted to the NDA as a supportive trial.

“The positive results of TRANQUILITY-2 are expected to complete the most comprehensive dry eye disease NDA submission to date,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “I want to express my sincere gratitude to the principal investigators and more than 1,700 patients who have participated in clinical trials of reproxalap over the past five years, as well as our stockholders and other stakeholders for their continued confidence in Aldeyra. For many of the more than 39 million U.S. adults who suffer from dry eye disease, we believe the need for a rapidly acting therapy with a novel mechanism of action is significant. We are confident in the potential of reproxalap to meet that need.”

Conference Call Information

Aldeyra will host a conference call to discuss this announcement at 8:00 a.m. ET today, June 8, 2022. The dial-in numbers are (844) 200-6205 for domestic callers and (929) 526-1599 for international callers. The access code is 879247. A live webcast of the conference call will also be available on the “Investors & Media” section of the Aldeyra website at https://ir.aldeyra.com. Presentation slides, which contain material information and should be reviewed in conjunction with this press release, will be available on the investor relations page prior to the start of the conference call and webcast.

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

About Reproxalap

Reproxalap is a first-in-class small-molecule modulator of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap’s mechanism of action has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect 39 million or more adults in the United States.[1] 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.[2] By diminishing RASP levels, Aldeyra's lead RASP modulator reproxalap represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

About Aldeyra

Aldeyra develops innovative therapies designed to treat immune-mediated diseases. Our approach is to discover 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. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in late-stage clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 clinical testing for the treatment of systemic immune-mediated diseases. Our pipeline also includes ADX-2191 (intravitreal methotrexate 0.8%), in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. For more information, visit https://www.aldeyra.com/ and follow us on LinkedIn, Facebook, and Twitter.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the timing and submission of a potential NDA; the anticipated timing of enrollment and results from Aldeyra's clinical trials; expectations regarding the timing and results of the expected Type B Pre-NDA meeting, including the FDA's acceptance of Aldeyra's post-hoc review of data and agreement with Aldeyra's methods of analyzing data; and Aldeyra's projected cash runway. 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, enrollment or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, 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 in clinical trials focused on the same or on different indications; 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; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) and obtain reimbursement for Aldeyra's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, 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, 2021, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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[1] Company estimates and 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.

[2] Choi W, Lian C, Ying L, Kim GE, You IC, Park SH, Yoon KC. Expression of Lipid Peroxidation Markers in the Tear Film and Ocular Surface of Patients with Non-Sjogren Syndrome: Potential Biomarkers for Dry Eye Disease. Curr Eye Res. 2016 Sep;41(9):1143-9. doi: 10.3109/02713683.2015.1098707. Epub 2016 Jan 5. PMID: 26731289.

Contacts

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ALDX@investorrelations.com