

**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): September 11, 2017

ALDEYRA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36332
(Commission File No.)

20-1968197
(IRS Employer Identification No.)

131 Hartwell Avenue, Suite 320
Lexington, MA 02421
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 1.01. Entry into a Material Definitive Agreement.

On September 11, 2017, Aldeyra Therapeutics, Inc. (“Aldeyra” or the “Company”) executed a Lease Agreement (the “Office Lease”) with WLC Three VI, L.L.C. (“WLC”) for approximately 6,924 square feet of office space located at 131 Hartwell Avenue, 3rd Floor, Lexington, Massachusetts (the “Premises”). The Company intends to continue to use the Premises as its corporate headquarters. The Premises is comprised of two subsections: (i) approximately 3,736 square feet of rentable space (the “Phase I Premises”) and (ii) approximately 3,188 square feet of rentable space (the “Phase II Premises”). The Phase I Premises lease commences on November 1, 2017 and the Phase II Premises lease commences on January 1, 2018. The term with respect to the Premises shall be for a period ending on December 31, 2020, or as extended under the Company’s option to extend in the Office Lease. The Office Lease provides for a monthly base rent of \$7,316.33, increasing each year as indicated in the Office Lease. In addition to the base rent, the Company is required to pay WLC certain operating expenses, taxes and other fees in accordance with the terms of the Office Lease. The Office Lease contains customary representations and covenants regarding occupancy, maintenance and care of the Premises. The Company will post an initial security deposit in the amount of \$40,678.50.

The foregoing description of the Office Lease does not purport to be complete and is qualified in its entirety by the full text of the Office Lease, a copy of which will be filed as an exhibit to the Company’s quarterly report on Form 10-Q for the quarter ending September 30, 2017.

Item 7.01. Regulation FD Disclosure.

On September 12, 2017, management of Aldeyra will hold a conference call at 8:00 am ET to discuss data from its multi-center, double-blind, randomized Phase 2a clinical trial of topical ocular ADX-102 for the treatment of Dry Eye Disease (DED). A copy of the presentation being used in connection with this conference call is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, 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 September 12, 2017, Aldeyra issued a press release announcing data from its multi-center, double-blind, randomized Phase 2a clinical trial of topical ocular ADX-102 for the treatment of DED. A copy of Aldeyra’ press release is attached hereto as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Aldeyra Therapeutics, Inc. Presentation dated September 12, 2017
99.2	Aldeyra Therapeutics, Inc. Press Release dated September 12, 2017

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, M.D., Ph.D.

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

Title: President and Chief Executive Officer

Dated: September 12, 2017



Dry Eye Disease Phase 2a Results

September 12, 2017

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, trends, 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. 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 and clinical plans for Aldeyra's product candidates 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 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at 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 presentation is provided only as of September 12, 2017, 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.

Dry Eye Disease Phase 2a Data Highlights

- Statistically significant and clinically relevant improvement in multiple dry eye disease signs and symptoms
- Rapid onset of activity within one week of dosing
- Improvement increased over time, and a modest dose-response was observed, supporting activity of ADX-102
- Pro-inflammatory aldehyde levels reduced, supporting novel mechanism of ADX-102
- Primary objective of trial achieved: 0.1% ADX-102, which demonstrated consistent statistically and clinically significant activity and was the best-tolerated formulation, selected to advance to Phase 2b testing
- No safety concerns observed

Dry Eye Disease Phase 2a Clinical Design

Groups	Topical Ocular ADX-102 Formulations: <ul style="list-style-type: none">• 0.1% ADX-102• 0.5% ADX-102• 0.5% (Lipid) ADX-102
Randomization	1:1:1 28-Day Four-Times-Daily Dosing
Enrollment	51 Patients with Dry Eye Disease
Primary Objective	Dose Selection for Phase 2b Based on Tolerability and Exploratory Efficacy
Endpoints	Standard Dry Eye Disease Signs and Symptoms

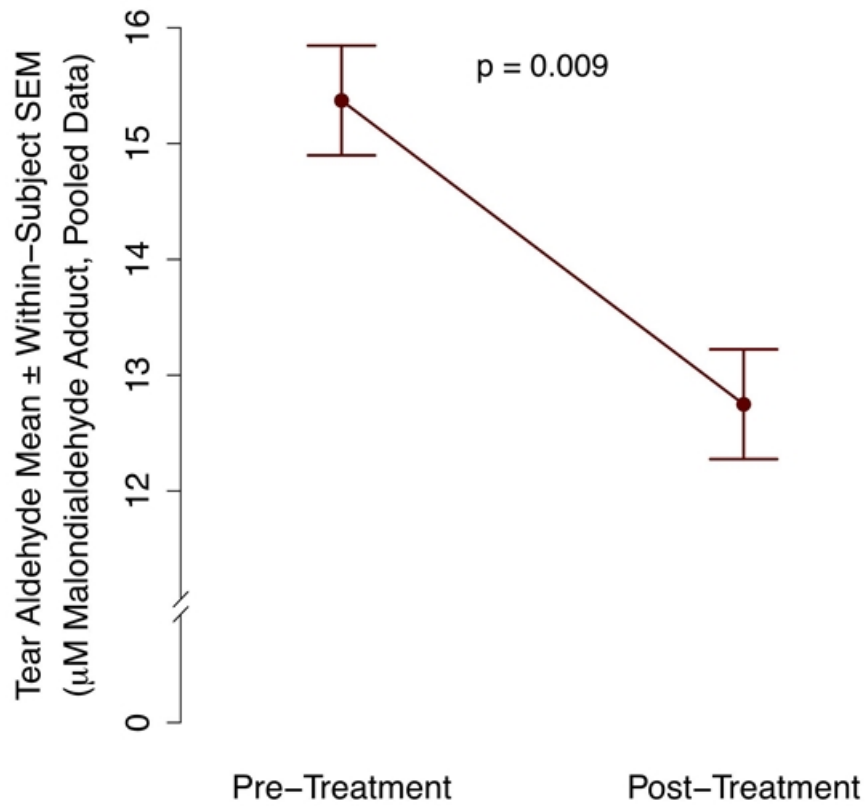
Further information can be found on www.clinicaltrials.gov: Trial #NCT03162783.

Statistically Significant Improvement in Multiple Dry Eye Disease Signs and Symptoms

Endpoint (Pooled Data)	Pre-Treatment	Post-Treatment	p value*
Symptom Assessment in Dry Eye (SANDE) Score	61	52	p = 0.003
Ocular Discomfort Score	2.3	1.5	p = 0.00002
Overall 4-Symptom Score	2.6	2.0	p = 0.0004
Tear Volume (Schirmer Test)	5.6	8.3	p = 0.008
Osmolarity	304	294	p = 0.003
Total Staining (Lissamine Green)	5.2	4.3	p = 0.002

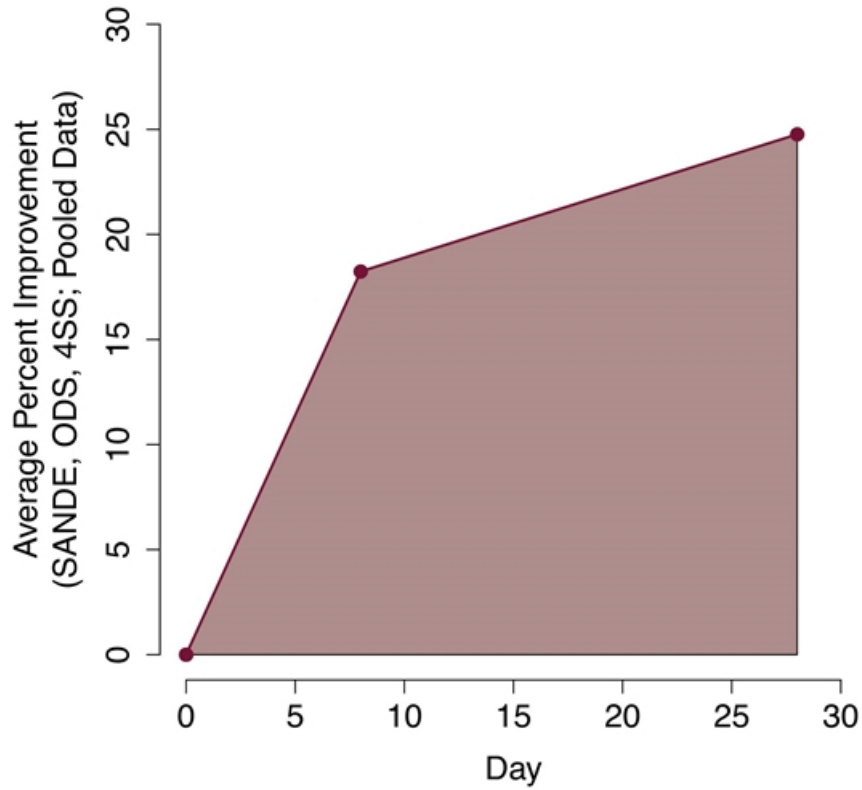
p values are subject to change based on quality control analysis; Pre-Treatment = Day 0, Post-Treatment = Day 28.

Tear Aldehyde Reduction Supportive of ADX-102 Aldehyde Sequestering Mechanism



p values are subject to change based on quality control analysis; Pre-Treatment = Day 0, Post-Treatment = Day 28.

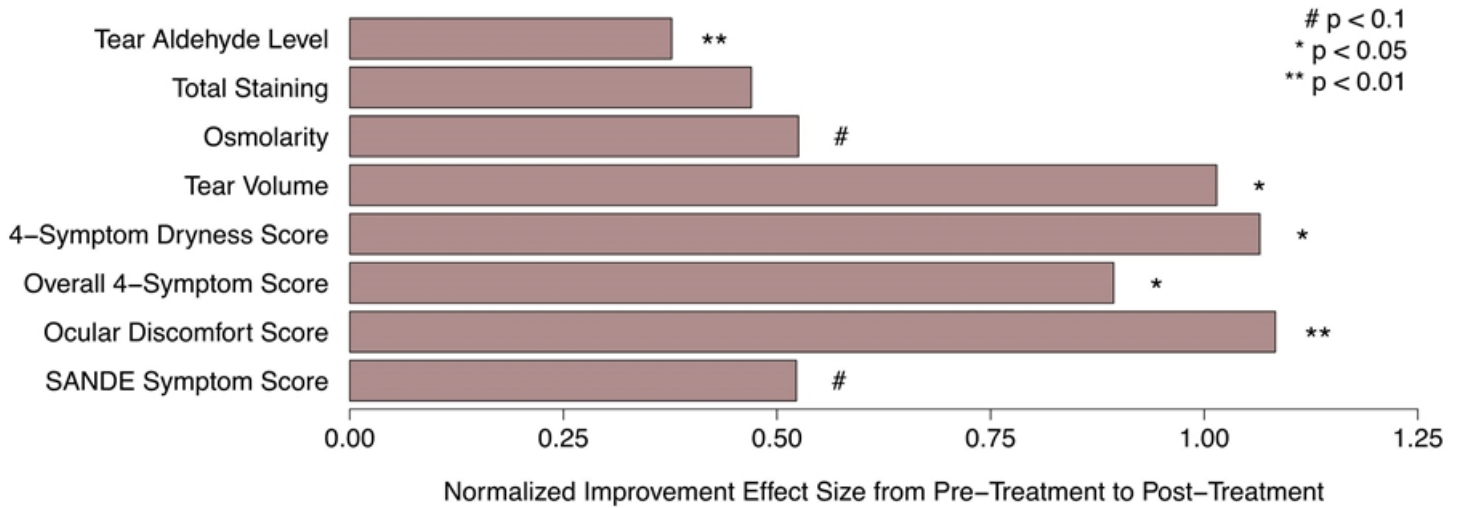
Symptom Improvement Over Time Supportive of Drug Activity



SANDE=Symptom Assessment in Dry Eye Score, ODS=Ocular Discomfort Score,
4SS=Overall 4-Symptom Score

Improvement Effect Sizes Are Robust and Statistically Significant

0.1% ADX-102 Improvement Effect Size Across Dry Eye Disease Signs and Symptoms



p values are subject to change based on quality control analysis; Effect size = Mean difference from Day 0 to Day 28 / Standard Deviation of Day 0.

Dose Selection for Phase 2b Clinical Testing

- No observed safety concerns
- Stinging consistent with other eye drops and prior ADX-102 clinical experience, generally resolving within minutes
- Tolerability of 0.1% ADX-102 consistent with standard of care, and was better than that of 0.5% ADX-102 formulations in the dry eye disease patient population
- 0.1% ADX-102, which demonstrated consistent statistically and clinically significant activity and was the best-tolerated formulation, selected to advance to Phase 2b clinical testing in dry eye disease

Dry Eye Disease Expected Phase 2b Clinical Design*

Groups	0.1% ADX-102, 0.25% ADX-102, and Control
Randomization	1:1:1 Double-Masked
Treatment Time	12 Weeks
Enrollment	225 Patients with Dry Eye Disease
Endpoints	Standard Dry Eye Disease Signs and Symptoms

*Pending additional non-clinical data, funding, and other factors, which may not be in Aldeyra's control

Dry Eye Disease Results Strategic Implications

- A novel mechanism of action with confirmed clinically relevant activity suggests that ADX-102 offers a differentiated approach for treatment of dry eye disease patients, which accounted for approximately \$1.8B in 2016 US prescription sales*.
- Positive dry eye disease efficacy results, combined with clinically relevant results in allergic conjunctivitis and noninfectious anterior uveitis, reinforce the anti-inflammatory potential of Aldeyra's novel aldehyde trap platform in ophthalmology.
- Clinical results to date suggest the potential to position ADX-102 as the only non-corticosteroid eye drop with efficacy in dry eye disease and allergic conjunctivitis, a substantial unmet medical need for large numbers of patients that suffer from both conditions.
- Based on the positive results, Aldeyra plans to advance to Phase 2b clinical testing in dry eye disease.

Aldeyra R&D Day October 10, 2017

Expected 2018 Clinical Trial Milestones*

		Product Candidate	Phase	Milestone
Ocular Inflammation		Noninfectious Anterior Uveitis	Phase 3	Results 2H18
		Allergic Conjunctivitis	Phase 3	Initiation 1H18 Results 2H18
		Dry Eye Disease	Phase 2b	Initiation 1H18 Results 2H18
Inborn Errors of Aldehyde Metabolism		Sjögren-Larsson Syndrome (SLS)	Phase 3 (Derm, Part I)	Initiation 1H18 Results 2H18
		Systemic ADX-10X [†]	Phase 1-2 (SLS, Inflammation)	Initiation 2H18

*Pending regulatory agency discussions, additional non-clinical data, funding, and other factors, which may not be in Aldeyra's control

[†]Timing contingent on product candidate selection and additional non-clinical data

**Aldeyra Therapeutics Announces Positive Results from Dry Eye Disease
Phase 2a Clinical Trial**

Statistically and Clinically Significant Improvement Across Multiple Sign and Symptom Endpoints

Onset of Action Observed Within One Week of Therapy

Phase 2b Clinical Trial Expected to be Initiated in the First Half of 2018

LEXINGTON, Mass., September 12, 2017 /PRNewswire/ — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to endogenous aldehyde toxicity, today announced positive results from a Phase 2a clinical trial of topical ocular ADX-102 in patients with dry eye disease.

“ADX-102 is a promising agent for the treatment of dry eye disease, a persistently challenging condition for many people worldwide,” commented John Sheppard, M.D., Professor of Ophthalmology, Eastern Virginia Medical School. “The evidence of rapid-onset activity and the tolerability profile demonstrated in the Phase 2a clinical trial suggests that ADX-102 could provide important patient benefits relative to existing therapies.”

The randomized, dose-ranging, parallel-group, double-masked Phase 2a clinical trial investigated three formulations of ADX-102 (0.1% ophthalmic solution, 0.5% ophthalmic solution, and 0.5% lipid formulation) in 51 dry eye disease patients (17 per arm) treated for 28 days. The results from the pooled data over the 28-day treatment period demonstrated statistically significant improvement from baseline in Symptom Assessment in Dry Eye (SANDE) Score (p=0.003), Ocular Discomfort Score (p=0.00002), Overall Four-Symptom Score (p=0.0004), Schirmer (tear volume) Test (p=0.008), tear osmolarity (p=0.003), and Lissamine Green ocular surface staining score (p=0.002). Improvements in dry eye disease signs and symptoms were evident within one week of therapy. A modest dose-response was observed, and activity increased over the duration of therapy, supporting evidence of the effect of drug. Levels of malondialdehyde, a pro-inflammatory aldehyde mediator sequestered by ADX-102, were significantly reduced in the tears of patients (p=0.009), supporting the differentiated mechanism of action relative to other therapies in dry eye disease.

The primary objective of the trial was to select a formulation and dose range for a Phase 2b clinical trial. Based on consistent statistically and clinically significant activity across multiple sign and symptom endpoints, and tolerability consistent

with that of standard of care, 0.1% ADX-102 was nominated for advancement. Relative to baseline, improvement after 28 days of 0.1% ADX-102 therapy was statistically significant or approached statistical significance for Ocular Discomfort Score ($p=0.002$), the dryness component of the Four-Symptom Score ($p=0.01$), Overall Four-Symptom Score ($p=0.048$), SANDE Score ($p=0.09$), Schirmer Test ($p=0.04$), tear osmolarity ($p=0.06$), and tear aldehyde levels ($p=0.007$). Effect sizes generally correlated with clinical significance for patient-reported outcomes.

There were no safety concerns observed for any of the formulations of ADX-102, and no serious adverse events were reported.

“These data represent the fourth set of positive Phase 2 results with ADX-102 in ocular inflammation. The breadth of activity across noninfectious anterior uveitis, allergic conjunctivitis, and now dry eye disease confirms the potential of ADX-102 as an important and differentiated therapy in ophthalmology,” commented Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “We are particularly excited about the potential of ADX-102 in the dry eye disease population, which is generally perceived to be inadequately treated but accounted for approximately \$1.8 billion in prescription sales in the United States in 2016. We look forward to the initiation of a Phase 2b clinical trial in dry eye disease in the first half of 2018.”

Conference Call

Aldeyra will hold a conference call on September 12, 2017 at 8:00 a.m. ET to discuss results of the clinical trial. The dial-in numbers are 1-877-870-4263 for domestic callers and 1-412-317-0790 for international callers. A live webcast of the conference call will also be available on the investor relations page of Aldeyra’s corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on Aldeyra’s website for one year.

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc. is a biotechnology company devoted to improving lives by inventing, developing and commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. Aldeyra’s lead product candidate, ADX-102, is an aldehyde trap in development as topical eye drops for the treatment of ocular inflammation. ADX-102 has now been tested in over 250 patients in Phase 2 clinical trials in dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis. A dermatologic form of ADX-102 is in late-stage clinical development for the treatment of ichthyosis due to Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism. ADX-102 has not been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate. In patients with dry eye disease, pro-inflammatory aldehyde mediators may contribute to ocular inflammation. By diminishing aldehyde levels, Aldeyra's topical ocular aldehyde trap platform represents a novel and differentiated approach for the treatment of dry eye disease.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's plans and expectations for the development of ADX-102 and the timing thereof; the potential of ADX-102 as an agent for the treatment of dry eye disease; the ability of ADX-102 to provide important patient benefits and a differentiated mechanism of action relative to existing therapies; and estimates of the market size for Dry Eye Disease. 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 "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "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. 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, the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to establish and maintain development partnerships; 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, 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. 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.

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.

Corporate Contact:
Stephen Tulipano
Aldeyra Therapeutics, Inc.
Tel: +1 781-761-4904 ext. 205
stulipano@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
Chris.brinzey@westwicke.com

Media Contact:
Cammy Duong
MacDougall Biomedical Communications
781-591-3443
cduong@macbiocom.com