# 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 26, 2016**

# 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))

**Item 7.01. Regulation FD.**

On September 26, 2016, Aldeyra Therapeutics, Inc. ("Aldeyra") intends to make a slide presentation at its Research and Development Day in person in New York City and by webcast on Aldeyra's website. A copy of Aldeyra's slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

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

The information in Item 7.01 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless Aldeyra expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

**Item 8.01 Other Events.**

On September 26, 2016, Aldeyra issued a press release that provided an update on Aldeyra's clinical development plans. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Slide presentation of Aldeyra Therapeutics, Inc. dated September 26, 2016. |
| 99.2 | Press Release of Aldeyra Therapeutics, Inc. dated September 26, 2016. |

**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.

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 26, 2016


*A Novel Pharmaceutical Platform Focused on Inflammation and Rare Inborn Errors of Metabolism*

Research and Development Day
September 26, 2016

# 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 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, 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. 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, 2015 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may also be set forth in Aldeyra's Quarterly Report on Form 10-Q for the quarter ending September 30, 2016, to be filed with the SEC in the fourth quarter of 2016.
- 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 26, 2016, 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 THERAPEUTICS™

# Agenda

- **Aldeyra R&D Highlights**
  - Todd Brady, M.D., Ph.D., CEO
  - David Clark, M.D., CMO
- **Aldehydes: A Novel Target in Human Disease**
  - Brian Day, Ph.D., Professor, Department of Medicine, Colorado School of Public Health
- **Ocular Inflammation: A Steroid-Sparing Approach**
  - John Sheppard, M.D., Professor of Ophthalmology, Eastern Virginia Medical School
- **Sjögren-Larsson Syndrome: An Inborn Error of Aldehyde Metabolism**
  - William Rizzo, M.D., Professor, Division of Inherited Metabolic Diseases, Nebraska Medical Center
- **Summary**

ALDEYRA THERAPEUTICS™

# R&D Highlights

Todd Brady, M.D., Ph.D.
Chief Executive Officer, President & Director
Aldeyra Therapeutics

ALDEYRA THERAPEUTICS™

# Research and Development Update

**In 2016, Aldeyra announced positive data in all three Phase II clinical trials**

- Clinical data in inflammation and an inborn error of aldehyde metabolism are first-in-class, and support aldehyde trapping as a novel therapeutic modality.

**Aldeyra is now a Phase III company: two different clinical programs expected to start in 2017**

- First-ever vehicle-controlled Phase III trial in noninfectious anterior uveitis
- First-ever Phase III trial in ichthyosis due to Sjögren-Larsson Syndrome

**Aldeyra's program in allergic conjunctivitis expected to advance to Phase IIb in 2017**

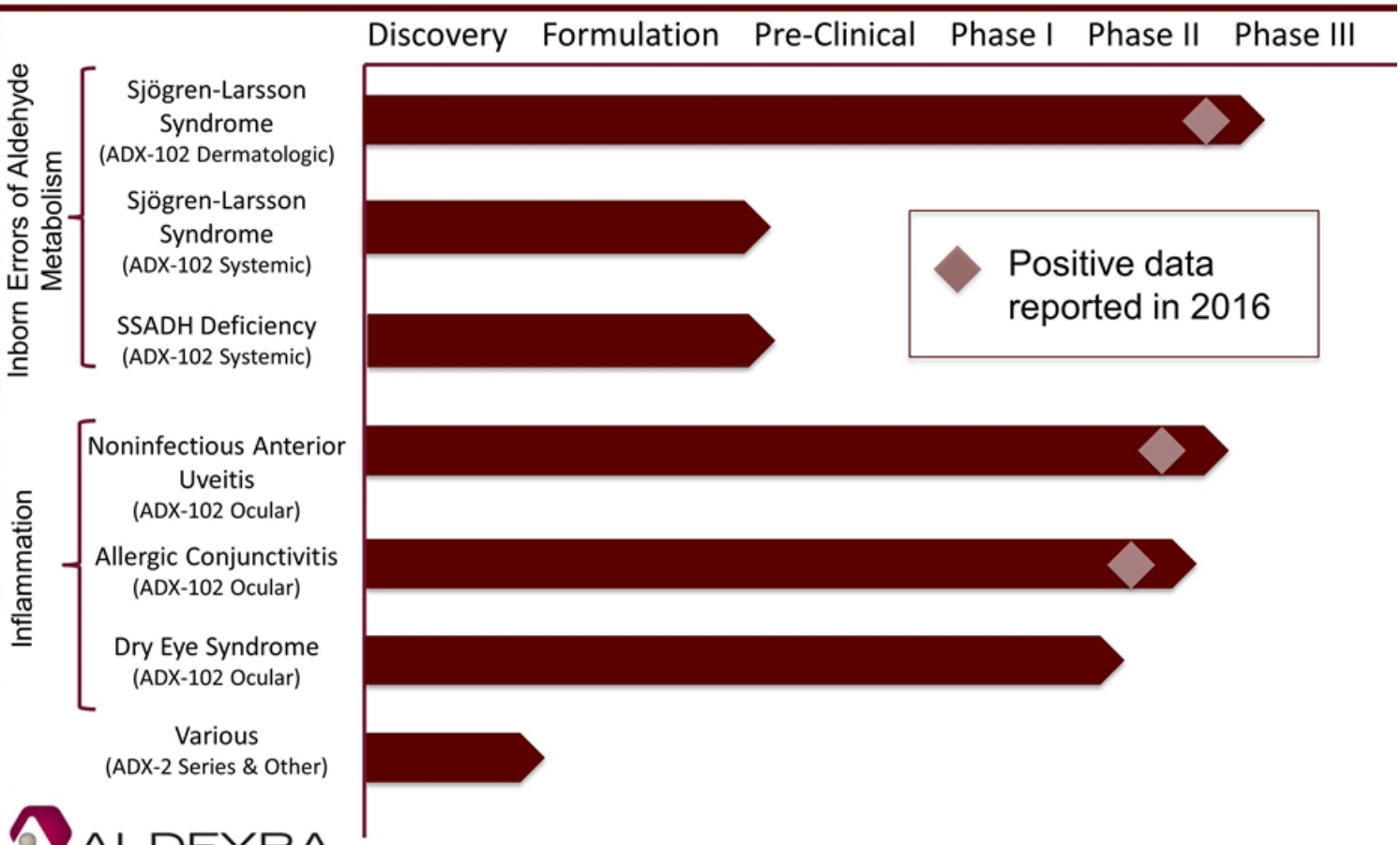
- Phase IIb vehicle-controlled dose-ranging trial of ocular itching following allergen challenge, the same design previously used for pivotal clinical trials

**A new ocular inflammation trial: Dry Eye Syndrome Phase IIa planned for 2017**

- Novel formulations of topical ocular ADX-102 (formerly NS2) to be tested

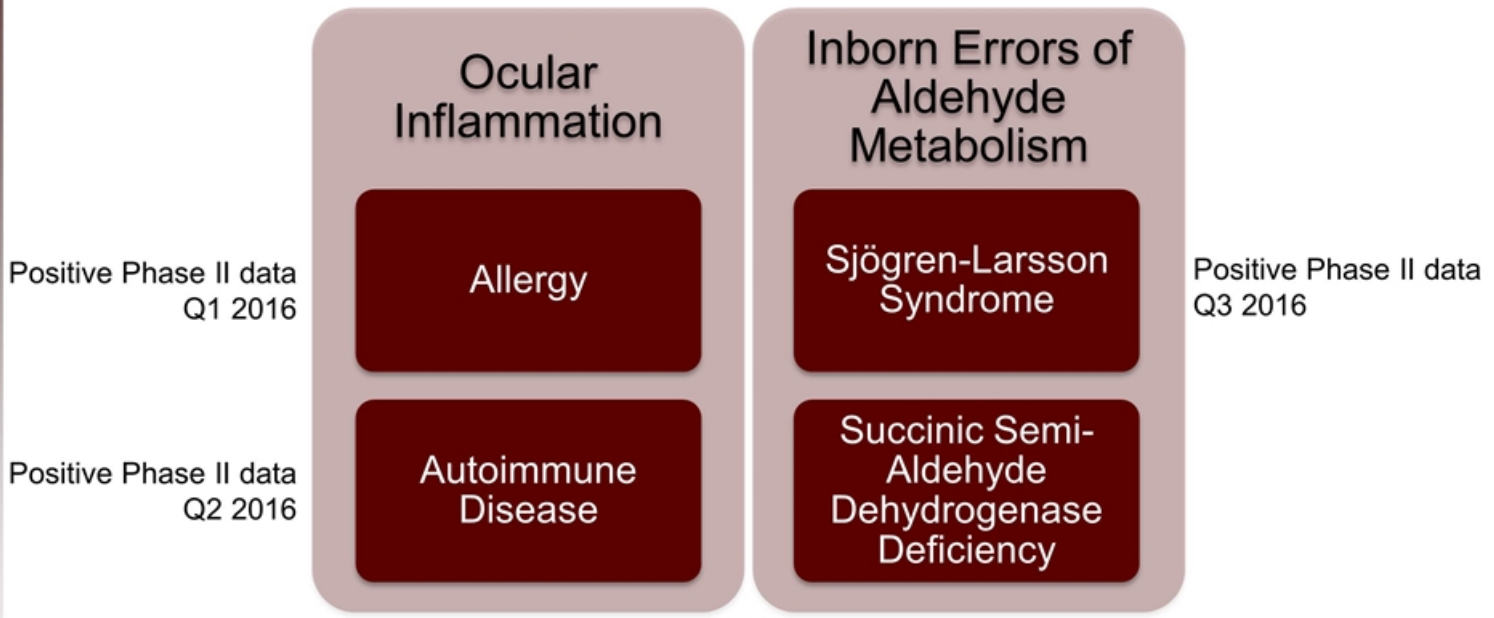
ALDEYRA THERAPEUTICS™

# A Robust Pipeline with Recent Clinical Success




ALDEYRA THERAPEUTICS™

# A Clinically Validated Therapeutic Platform with Multiple Potential Value Drivers




Aldehyde trapping represents a novel and clinically validated potential therapeutic platform intended for the treatment of inflammation and inborn errors of aldehyde metabolism.

ALDEYRA THERAPEUTICS™

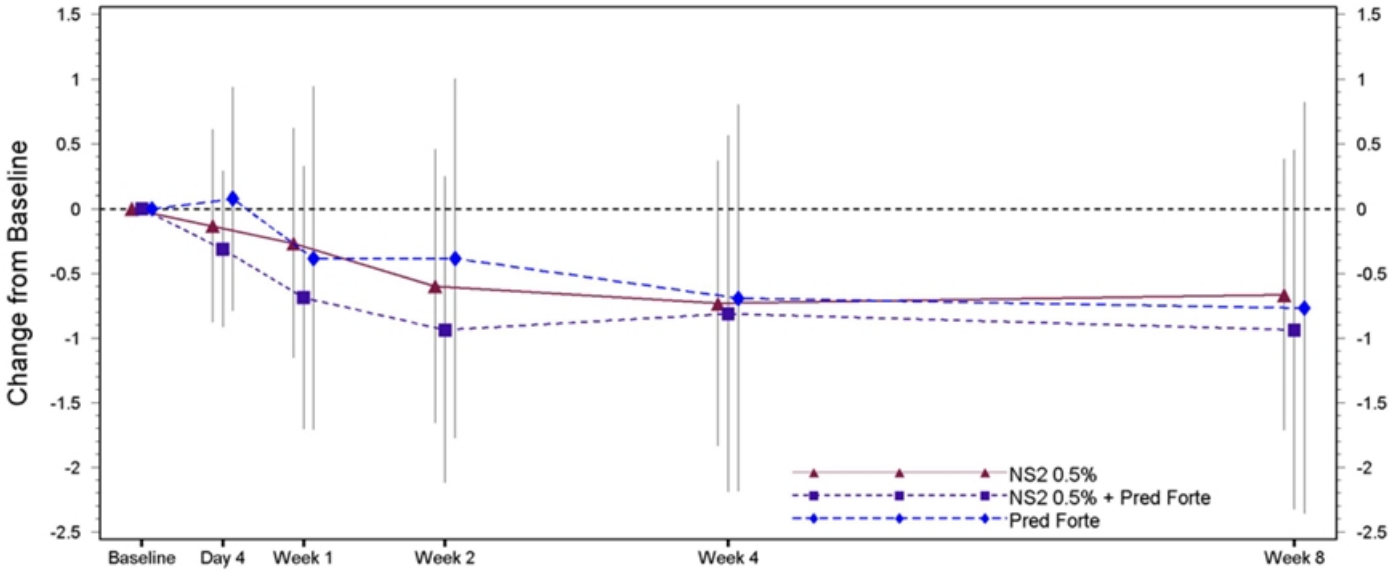
# Review of ADX-102 Data in Ocular Inflammation

David J. Clark, M.D., M.R.C.P., A.F.P.M.
Chief Medical Officer
Aldeyra Therapeutics

ALDEYRA THERAPEUTICS™

# ADX-102 Reduced Inflammation in Noninfectious Anterior Uveitis

Mean (±SD) Change from Baseline in Anterior Chamber Cell Grade over Time
(mITT Population*, Last Observation Carried Forward)



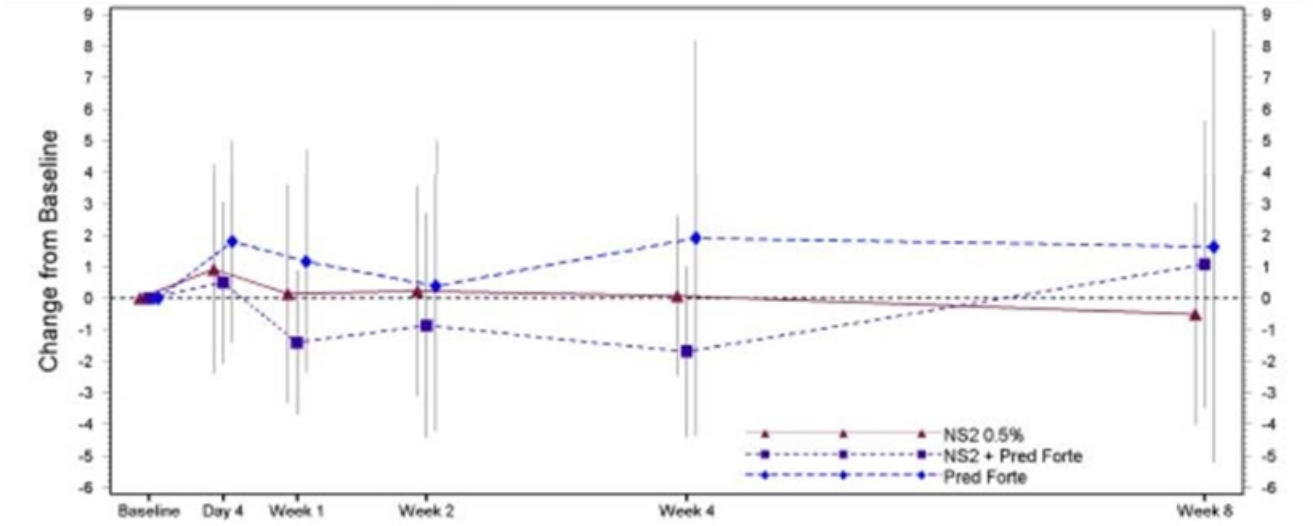

ADX-102 monotherapy effective in the treatment of noninfectious anterior uveitis, with an efficacy profile similar to Pred Forte monotherapy in this Phase II clinical trial

*Modified intent-to-treat population excludes one patient that was found to have history of ovarian cancer within past five years

ALDEYRA THERAPEUTICS™

# ADX-102 Did Not Increase Intraocular Pressure in Noninfectious Anterior Uveitis

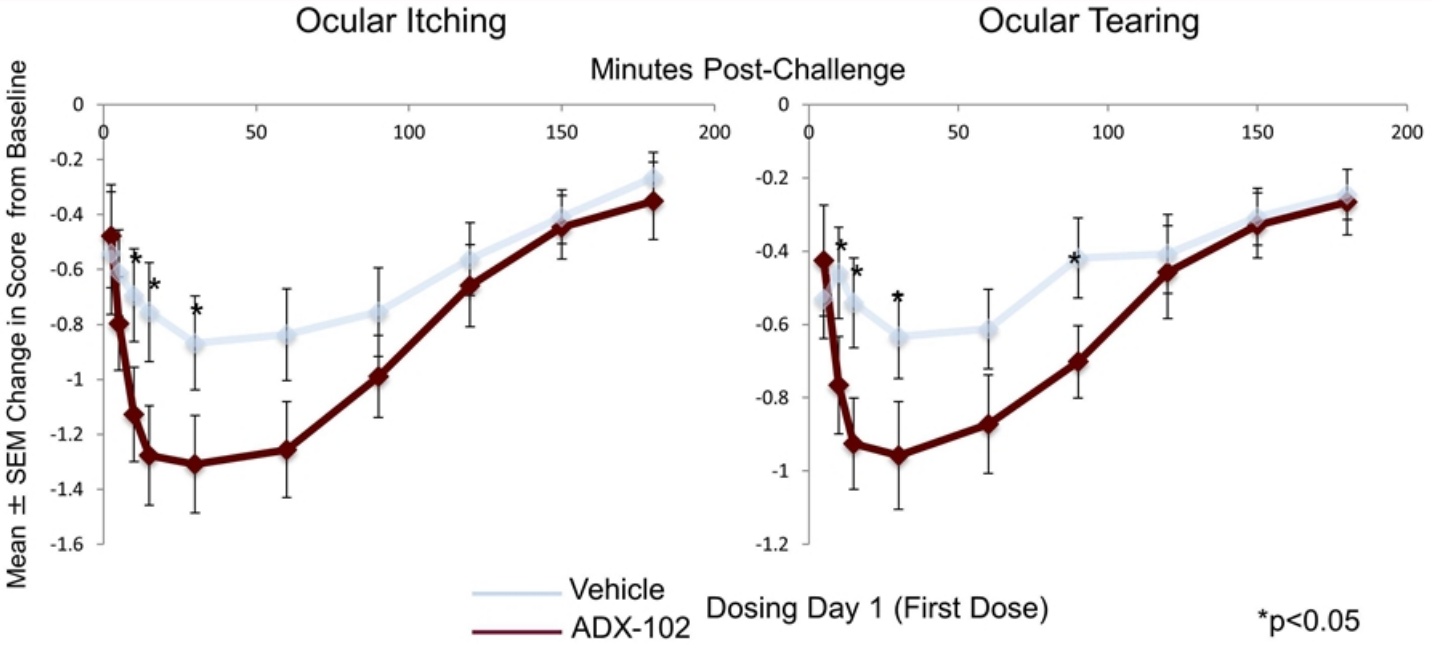
Mean (±SD) Change from Baseline in Intraocular Pressure (mmHg) over Time
(Safety Population)




Increase in intraocular pressure, which may lead to glaucoma, is a major toxicity of corticosteroids that was not apparent with ADX-102.

ALDEYRA THERAPEUTICS™

# ADX-102 Reduced Itching and Tearing in Allergic Conjunctivitis After a Single Dose




ADX-102 achieved reductions in ocular itching and tearing that were clinically relevant and statistically greater than vehicle in this Phase II clinical trial.

ALDEYRA THERAPEUTICS™

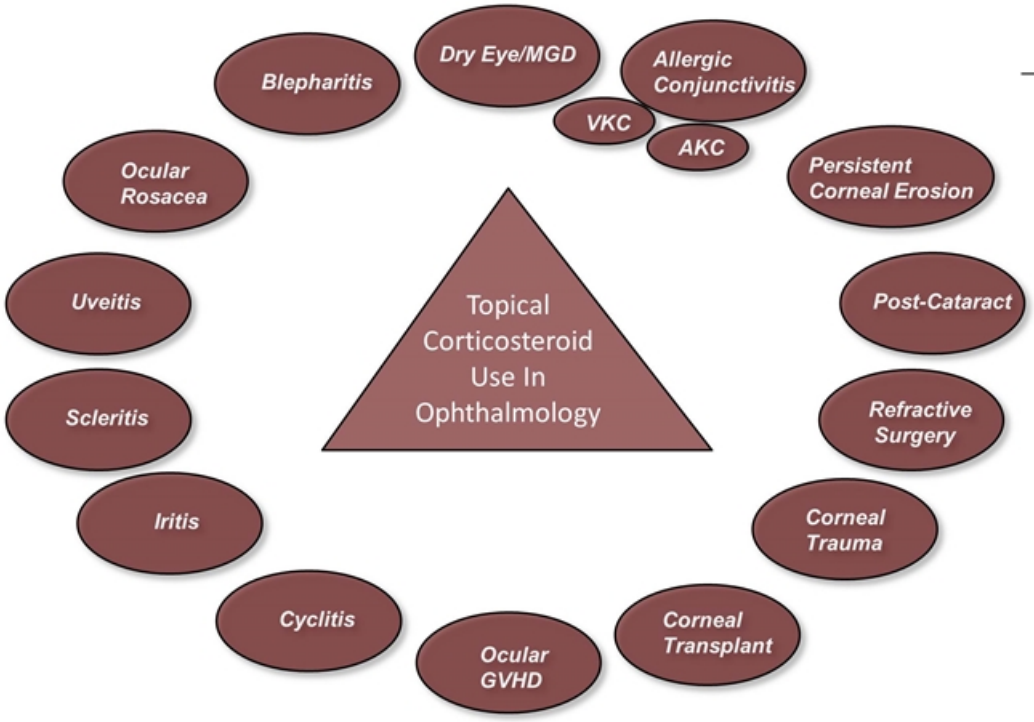
# Highlights of Clinical Trials Expected to Start in 2017

- Phase III noninfectious anterior uveitis
  - Vehicle-controlled, up to 45 subjects per arm
  - Data expected in 2018 H2*
- Phase IIb allergic conjunctivitis
  - Dose-ranging (two doses + modified vehicle), up to 50 subjects per arm
  - Data expected in 2017 H2*
- Phase IIa dry eye syndrome
  - Multiple ADX-102 topical ocular formulations, up to 30 subjects per arm
  - Data expected in 2017 H2*

*Pending clinical site and subject enrollment, institutional review board approvals, and other factors, which may not be in Aldeyra's control

ALDEYRA THERAPEUTICS™

# Significant Unmet Medical Need for Non-Steroidal Therapy




**Price Benchmarks**

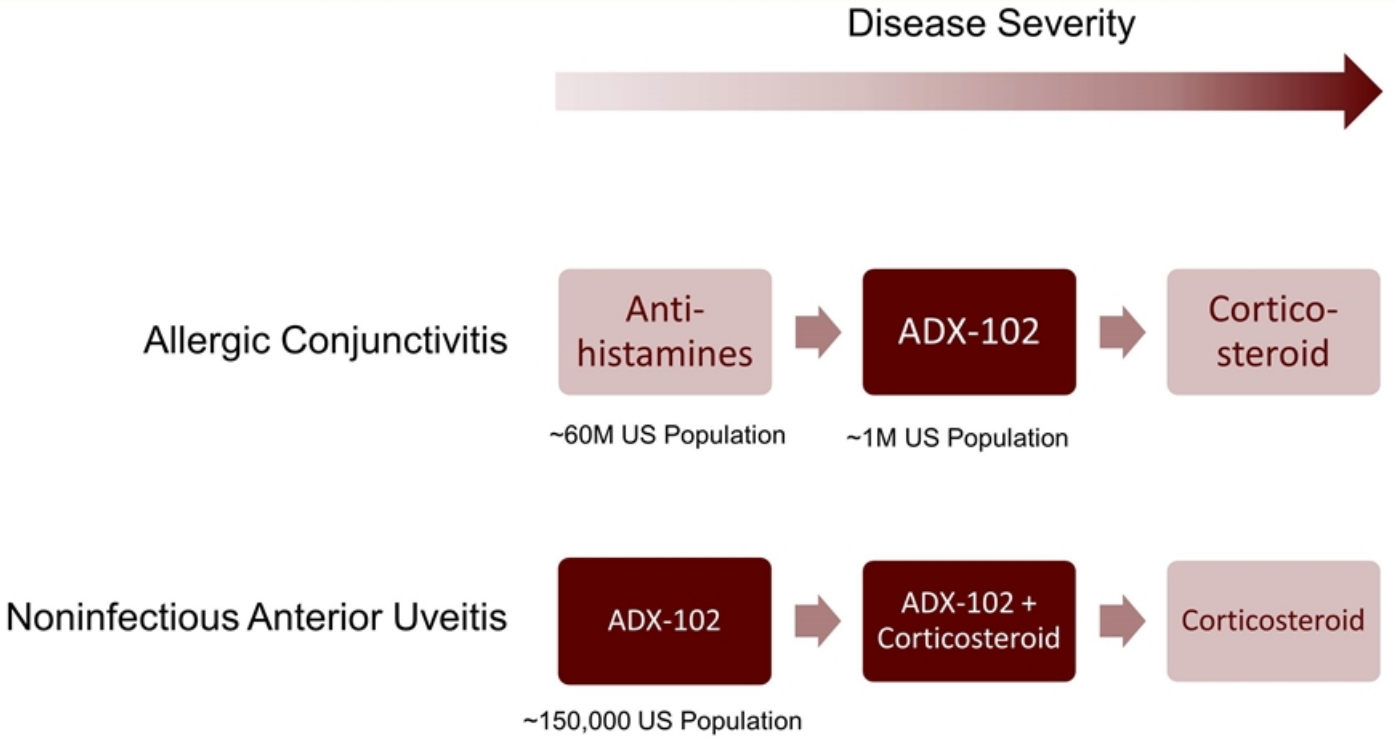
| Drug | Retail Price Point |
|---|---|
| Restasis<br>Xiidra | $400 - $500 (per month) |
| Lotemax<br>Durazol<br>Patanol<br>Pataday<br>Pred Forte<br>FML | $135 - $400 (per month/course) |
| Steroid Generics | <$75 (per month/course) |

2015 Topical Ocular Corticosteroid Sales = $1.5B (80% Branded, IMS Data)

MGD: Meibomian gland dysfunction, VKC: Vernal Keratoconjunctivitis, AKC: Atopic Keratoconjunctivitis

ALDEYRA THERAPEUTICS™

# ADX-102: A Potential First or Second-Line Approach in Ocular Inflammation




ALDEYRA THERAPEUTICS™

# Steroid Toxicity Expected to Allow for Premium Pricing of Novel Drugs in Ocular Inflammation

| | **Potential Side Effects of Therapy** |
|---|---|
| Corticosteroids | Cataracts, glaucoma, corneal ulceration, ocular infection |
| ADX-102 | No consistent side effects observed in noninfectious anterior uveitis Phase II clinical trial; mild and transient stinging in allergic conjunctivitis |


†Pending clinical data, regulatory approval, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control

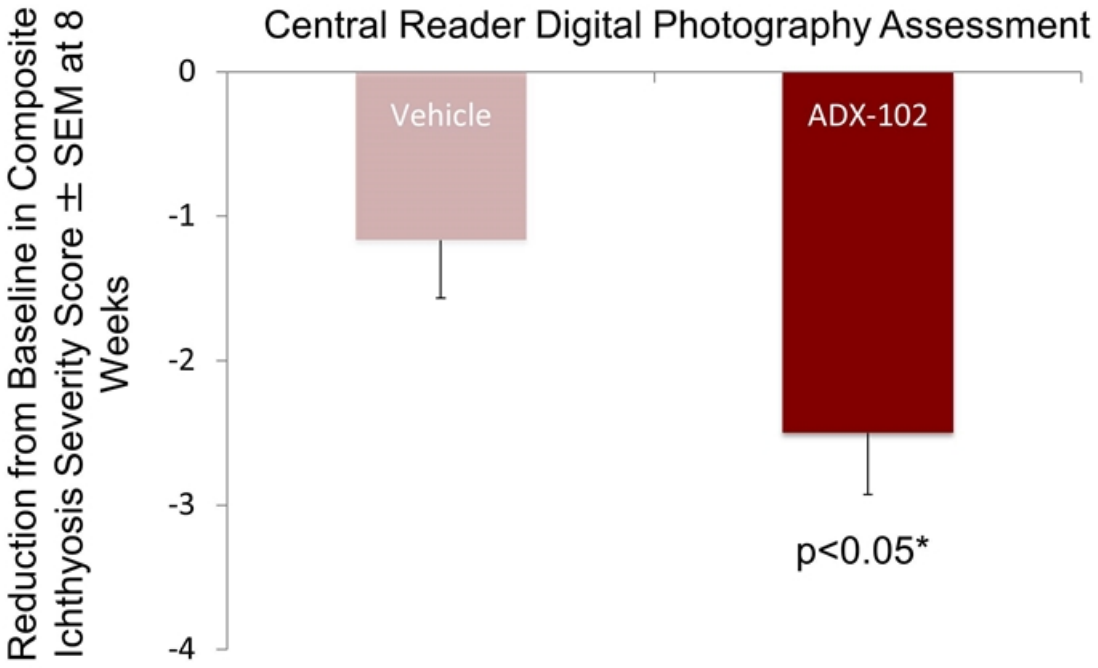
ALDEYRA THERAPEUTICS™

# Review of ADX-102 Data in SLS

David J. Clark, M.D., M.R.C.P., A.F.P.M.
Chief Medical Officer
Aldeyra Therapeutics

ALDEYRA THERAPEUTICS™

# Statistically Significant Reduction in Ichthyosis Severity Score

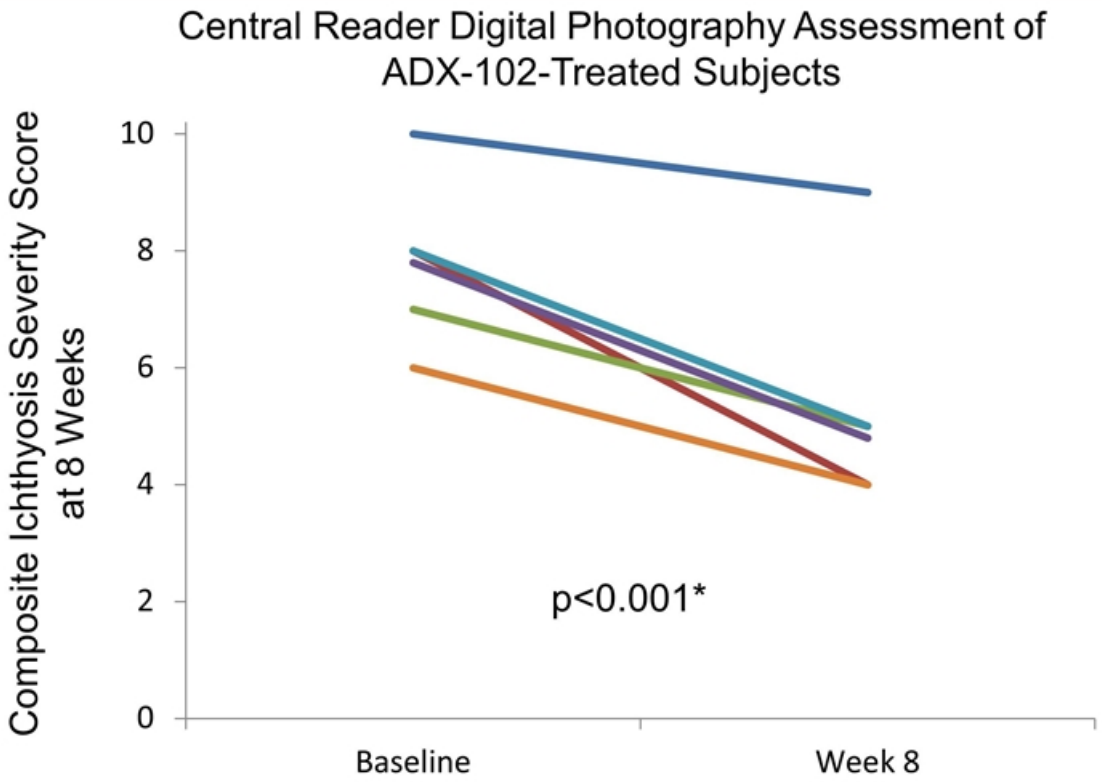



In a Phase II clinical trial, ADX-102 reduced ichthyosis severity in a manner that is statistically superior to vehicle.

*p values are subject to change based on quality control analysis

ALDEYRA THERAPEUTICS™

# Every Treated Subject Improved in a Phase II Clinical Trial




*p values are subject to change based on quality control analysis

ALDEYRA THERAPEUTICS™

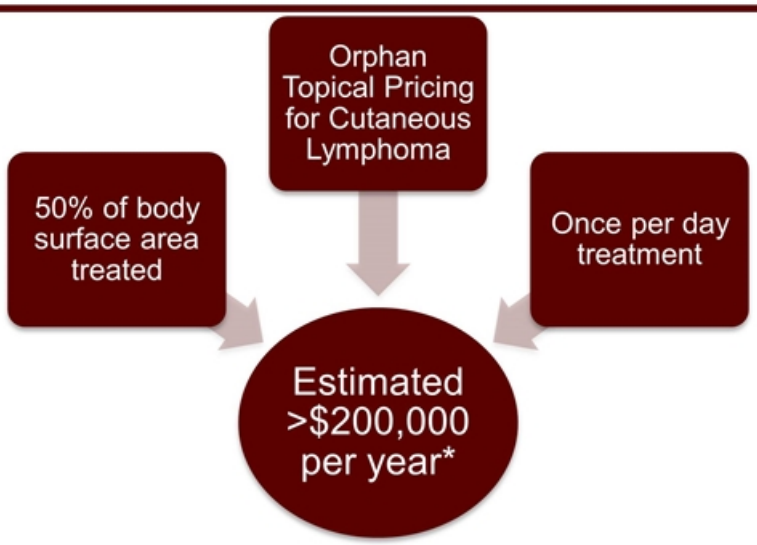
# Clinical Development Plans*

- Phase III Sjögren-Larsson Syndrome Dermatologic, Expected initiation 2017 H1
  - Pivotal design pending FDA/EMA feedback, estimated 20-30 subjects
- ADX-102 systemic lead oral formulation selected; IND filing planned for 2017 H2
- Inborn errors of aldehyde metabolism: Sjögren-Larsson Syndrome and Succinic Semi-aldehyde Dehydrogenase Deficiency
  - Biomarker-based Phase IIa clinical trials
  - Estimated 5-10 subjects per trial
  - Initiation expected in 2018 H1

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

ALDEYRA THERAPEUTICS™

# Lifelong Therapy for Sjögren-Larsson Syndrome




**Estimated 0.4 births/100,000 (about 1000 patients in US)†**
**Total US SLS market: ~$200M**

**Managed Care Qualitative Market Research of NS2 as a Potential Topically Applied Treatment for the Dermatologic Aspects of Sjögren-Larsson Syndrome*, CPD Research & Consulting; pricing pending clinical data, regulatory approval, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors.

†Extrapolating from a Swedish estimate in addition to a US genetic mutation analysis, it is generally assumed that there are approximately 1,000 SLS patients in the United States and a greater number of SLS patients in Europe

ALDEYRA THERAPEUTICS™

# Summary

Todd Brady, M.D., Ph.D.
Chief Executive Officer, President & Director
Aldeyra Therapeutics

ALDEYRA THERAPEUTICS™

# Target Indications with Significant Markets

| Disease | Unmet Medical Need | Clinical Data | Estimated US Patients | Potential Pricing† |
|---|---|---|---|---|
| Allergic Conjunctivitis | Steroid toxicity (glaucoma, cataracts, other) | Positive Phase IIa data Q1 2016 | 1,000,000 Steroid-dependent | $1,000/course |
| Noninfectious Anterior Uveitis | Steroid toxicity (glaucoma, cataracts, other) | Positive Phase II data Q2 2016 | 150,000 | $1,000/course |
| Sjögren-Larsson Syndrome | No FDA-approved Therapy | Positive dermatology data Q3 2016 | 1,000 | $200,000 per patient per year |
| SSADH Deficiency | No FDA-approved Therapy | Phase IIa data expected Q2 2018 | 250 | $200,000 per patient per year |

*Extrapolating from a Swedish estimate in addition to a US genetic mutation analysis, it is generally assumed that there are approximately 1,000 SLS patients in the United States and a greater number of SLS patients in Europe

†Pending clinical data, regulatory discussions, payor negotiations, competition, potential legislative changes, and other factors, which may not be in Aldeyra's control

ALDEYRA THERAPEUTICS™

# Research and Development Summary

**In 2016, Aldeyra announced positive data in all three Phase II clinical trials**

- Clinical data in inflammation and an inborn error of aldehyde metabolism are first-in-class, and support aldehyde trapping as a novel therapeutic modality.

**Aldeyra is now a Phase III company: two different clinical programs expected to start in 2017**

- First-ever vehicle-controlled Phase III trial in noninfectious anterior uveitis
- First-ever Phase III trial in ichthyosis due to Sjögren-Larsson Syndrome

**Aldeyra's program in allergic conjunctivitis expected to advance to Phase IIb in 2017**

- Phase IIb vehicle-controlled dose-ranging trial of ocular itching following allergen challenge, the same design previously used for pivotal clinical trials

**A new ocular inflammation trial: Dry Eye Syndrome Phase IIa planned for 2017**

- Novel formulations of topical ocular ADX-102 (formerly NS2) to be tested

ALDEYRA THERAPEUTICS™

# Questions

ALDEYRA THERAPEUTICS™

**Exhibit 99.2**

**Aldeyra Therapeutics Provides Update on Late-Stage Clinical Trials at 2016 Research and Development Day**

*First-Ever Vehicle-Controlled Phase III Clinical Trial in Noninfectious Anterior Uveitis*

*First-Ever Phase III Clinical Trial in Sjögren-Larsson Syndrome*

*Allergic Conjunctivitis Phase IIb Clinical Trial*

*Phase IIa Clinical Trial in Dry Eye Syndrome*

LEXINGTON, MA — (Marketwired) — 09/26/16 — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today provided updates on its plans for late-stage clinical trials at the Aldeyra 2016 Research and Development Day. Aldeyra announced plans for the first-ever vehicle-controlled Phase III clinical trial in noninfectious anterior uveitis, as well as a first-ever Phase III clinical trial in Sjögren-Larsson Syndrome. Aldeyra also announced the expected advancement of ADX-102 (formerly NS2) to a Phase IIb clinical trial in allergic conjunctivitis, and the addition of a clinical program in dry eye syndrome.

“Based on the positive results of all three of our Phase II clinical trials completed this year, we are excited to progress to late-stage clinical testing and embark upon pre-commercial planning as we enter a new phase of growth at Aldeyra,” said Todd C. Brady, M.D., Ph.D., President and CEO. “We look forward to advancing our first-in-class aldehyde trap platform in inflammation and inborn errors of aldehyde metabolism, two different classes of diseases with unmet medical need. In particular, patients with ocular inflammation suffer from cataracts, glaucoma, and other co-morbidities associated with repeated dosage of corticosteroids, and patients with Sjögren-Larsson Syndrome currently have no available approved therapies to treat the symptoms of their disease.”

A live webcast of the presentation and slide deck will be available via the Company’s Investor Relations website at http://ir.aldeyra.com. Following the live webcast, an archived version will be available on the website until September 25, 2017.

***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 for ocular inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism. Aldeyra’s product candidates have not been approved for sale in the U.S. or elsewhere.

***About Sjögren-Larsson Syndrome***

Sjögren-Larsson Syndrome (SLS) is a rare inborn error of aldehyde metabolism caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated toxic fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. No therapy for SLS has been approved by the U.S. Food and Drug Administration.

***About Noninfectious Anterior Uveitis***

Noninfectious anterior uveitis is a rare, potentially blinding disease that may be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia.

***About Allergic Conjunctivitis***

Allergic conjunctivitis is a common allergic disease that is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling and redness.

***About Dry Eye Syndrome***

Dry eye syndrome is a common inflammatory disease characterized by insufficient moisture and lubrication in the anterior surface of the eye. Symptoms may include ocular irritation, burning or stinging, and severe cases may lead to decreased vision. In patients with dry eye syndrome, aldehydes may contribute to ocular inflammation as well as the impairment of lipids (fats) that lubricate the surface of the eye.

***Safe Harbor Statement***

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, about Aldeyra's product candidates, strategy, future plans and prospects, including statements regarding Aldeyra's development plans for its product candidates and the structure and timing of Aldeyra's planned or pending clinical trials. 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, structure and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; 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 and determinations 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, 2015 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be set forth in Aldeyra's Quarterly Report on Form 10-Q for the quarter ending September 30, 2016, to be filed with the SEC in the fourth quarter of 2016.

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