
**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 5, 2014

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.)

15 New England Executive Park
Burlington, MA 01803
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 270-0630

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))
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Item 7.01. Regulation FD Disclosure

Aldeyra Therapeutics, Inc. (the “Company” or “Aldeyra”) will be making presentations at the 16th Annual Rodman & Renshaw Global Investment Conference, taking place September 8, 2014 through September 10, 2014 in New York, New York, and the Aegis Capital Corporation 2014 Healthcare and Technology Conference, taking place on September 10, 2014 through September 13, 2014 in Las Vegas, Nevada. The slides that will be used for these presentations are furnished as Exhibit 99.1 to this Current Report on Form 8-K. Aldeyra issued a press release on September 5, 2014 announcing the Company’s participation at these conferences, which is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

Various statements to be made during the presentations, including statements in the slides furnished as Exhibit 99.1 to this Form 8-K, are “forward-looking statements” under the securities laws. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “project,” “target,” “goal,” “likely,” “will,” “would,” and “could,” or the negative of these terms and similar expressions or words, identify forward-looking statements. 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 and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; the ability to obtain and maintain regulatory approval of 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; Aldeyra’s ability to attract or retain key personnel; and other factors that are described in the “Risk Factors” section of Aldeyra’s final prospectus filed under Rule 424(b)(4) with the Securities and Exchange Commission (the “SEC”) in connection with Aldeyra’s initial public offering and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 filed with the SEC on August 7, 2014. No forward-looking statements can be guaranteed and actual results may differ materially from such statements.

All written and verbal forward-looking statements attributable to Aldeyra or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Aldeyra cautions investors not to rely too heavily on the forward-looking statements Aldeyra makes or that are made on its behalf. The information conveyed during the presentation and in the slides attached as Exhibit 99.1 to this Form 8-K will be provided only as of the date on which such slides are presented, and the Company undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements contained in such presentations or slides from and after the date of such presentation whether as a result of new information, future events or otherwise.

The information in Item 7.01 of this Current Report on Form 8-K and the Exhibits 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation slides
99.2	Press Release

SIGNATURES

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

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady, M.D., Ph.D.

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

Title: President and Chief Executive Officer

Dated: September 5, 2014

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation slides
99.2	Press Release



*A Novel Pharmaceutical Platform
Focused on Trapping Aldehydes*

September 2014

- This presentation includes statements contains forward-looking statements that involve risks and uncertainties. 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,” “plan” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about: our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing; our anticipated growth strategies; our expectations regarding competition; the anticipated trends and challenges in our business and the market in which we operate; the timing and success of preclinical studies and clinical trials conducted by us and our development partners; the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing our product candidates; the size and growth of the potential markets for our product candidates and the ability to serve those markets; the rate and degree of market acceptance of any of our product candidates; our ability to establish and maintain development partnerships; our ability to attract or retain key personnel; our expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; and our ability to obtain and maintain intellectual property protection for our product candidates.
- Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Any forward-looking statement made by us in this presentation speaks only as of the date on which it is made. Except as required by law, we assume no obligation to update these statements publicly, or to update the reasons actual results could differ materially from those anticipated in these statements, even if new information becomes available in the future.
- Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operation, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in our final prospectus filed under Rule 424(b)(4) with the Securities and Exchange Commission on May 2, 2014 and in our subsequent filings with the Securities and Exchange Commission. In addition, even if our results of operation, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods.
- You should read carefully our filings with the Securities and Exchange Commission, including risk factors described therein, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements.

- **Todd Brady, M.D., Ph.D. – President, CEO, and Director**
 - 18 years of pharmaceutical business and clinical development
 - Domain Associates, Phenome Sciences, (acquired by Xanthus/Antisoma), Aderis Pharmaceuticals (acquired by Schwarz/UCB)
- **Scott Young – Chief Operating Officer**
 - 28 years of pharmaceutical clinical development
 - Genzyme, Genetics Institute, Oxigene, Repligen
- **Steve Tulipano, CPA – Chief Financial Officer**
 - 27 years of financial experience
 - Biogen, Javelin Pharmaceuticals

Board of Directors

Boyd Clarke – former CEO Aviron (acquired by MedImmune)

Gary Phillips, M.D. – Chief Strategy Officer Mallinckrodt Pharmaceuticals

Ben Bronstein, M.D. – former CEO Peptimmune (acquired by Genzyme)

Neal Walker, D.O. – CEO Aclaris Therapeutics

Marty Joyce – former CFO of Serono USA

Jesse Treu, Ph.D. – Domain Associates

Todd Brady – CEO Aldeyra Therapeutics

Unique, Innovative Platform Technology to Trap Aldehydes

- Orphan and mass-market diseases in which toxic aldehydes are implicated

Modest Funding Required for Multiple Clinical Events

- Lead compound in two topical indications: one dermal and one ocular
- Phase II/III results for Sjögren Larsson Syndrome (SLS) and Phase II results for acute anterior uveitis in 2015

Large Markets with Significant Unmet Medical Need

- Markets for orphan indications alone are substantial, and positive data may suggest efficacy in a broad array of mass-market diseases

Strong Patent Portfolio of Compositions, Uses, and Formulations

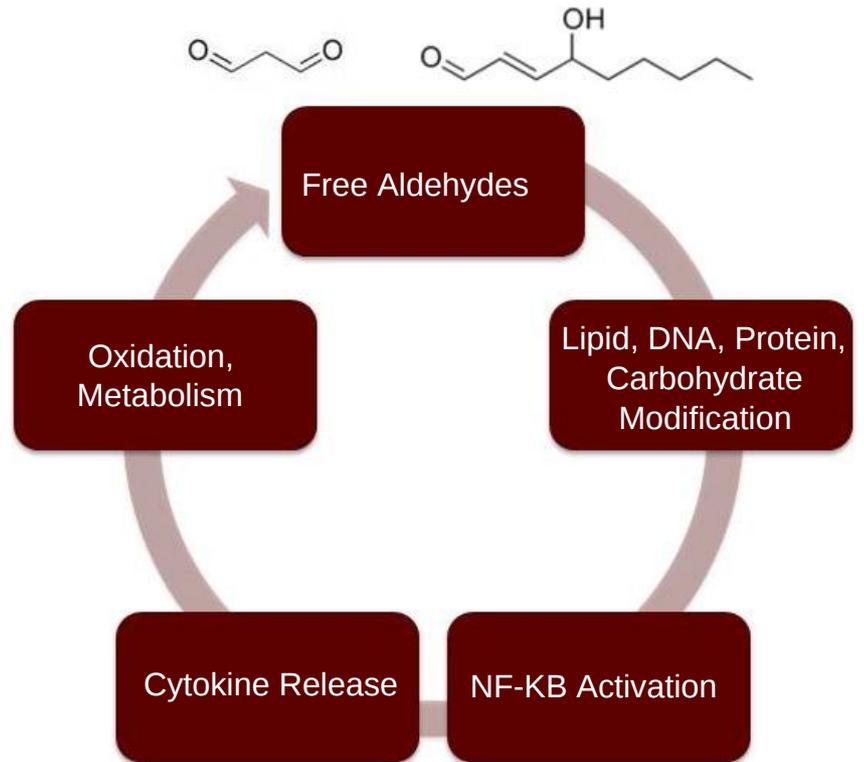
- Extend to late 2020s worldwide and to 2033 in US, assuming Hatch-Waxman extension

Marquee Investors Validate Opportunity

- Johnson & Johnson Development Corporation, Fidelity, and Domain Associates – one of the oldest and largest healthcare venture capital funds worldwide

Aldehydes Are Mediators of Disease

- Toxic mediators of numerous diseases
- Modify cellular constituents, lead to indigestible aggregates, and are pro-inflammatory
- Dehydrogenases attempt to eliminate free aldehydes
- High levels are implicated in autoimmune, inflammatory, neurological, cardiovascular and endocrinologic diseases



Aldehyde Traps: A Novel Therapeutic Approach

Aldehyde Binding

- Aldeyra's compounds rapidly trap free aldehydes

Adduct Transport

- Trapped aldehydes are transported to the lysosome

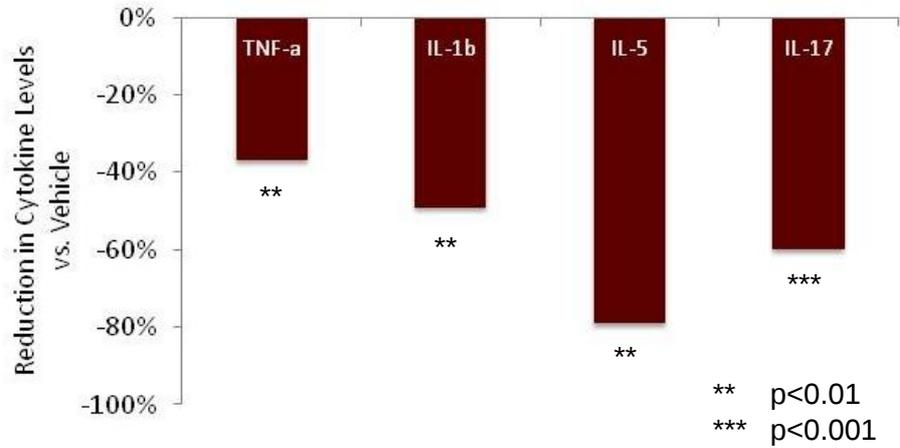
Cellular Disposal

- Drug and aldehydes are metabolized within hours

Aldeyra's lead aldehyde trap, NS2, appears to have minimal pharmacology; it does not seem to affect receptors or proteins. No similar technology believed to be available.

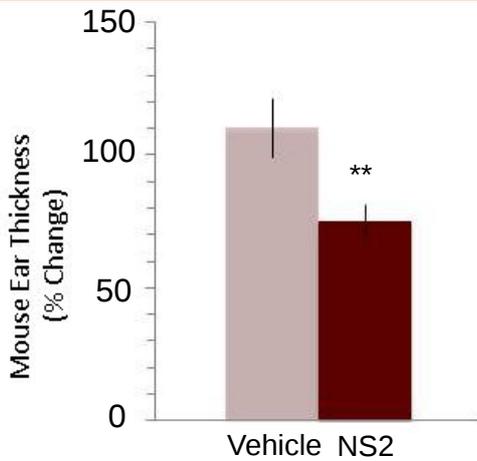
Trapping Aldehydes Generates a Broad Anti-Inflammatory Response

Mice treated with NS2 or vehicle 30 minutes prior to endotoxin exposure; cytokines measured two hours after endotoxin exposure

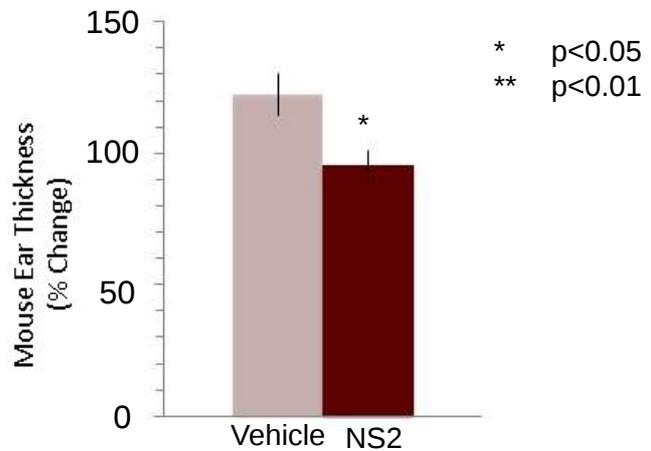


In an endotoxin model of cytokine generation in mice, NS2 administration significantly reduced levels of a broad array of pro-inflammatory cytokines.

NS2 Decreases Dermal Inflammation in Animal Models



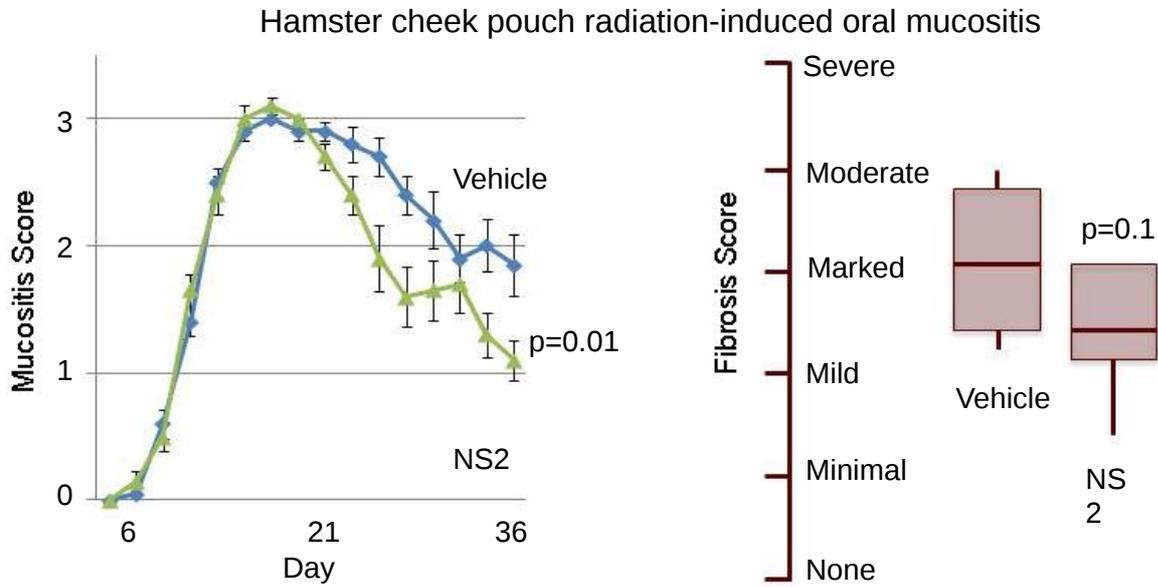
Murine Model of **Contact Dermatitis** (PMA)
6.5 hours after NS2 Administration



Murine Model of **Allergic Dermatitis** (Oxazolone)
24.5 hours after NS2 Administration

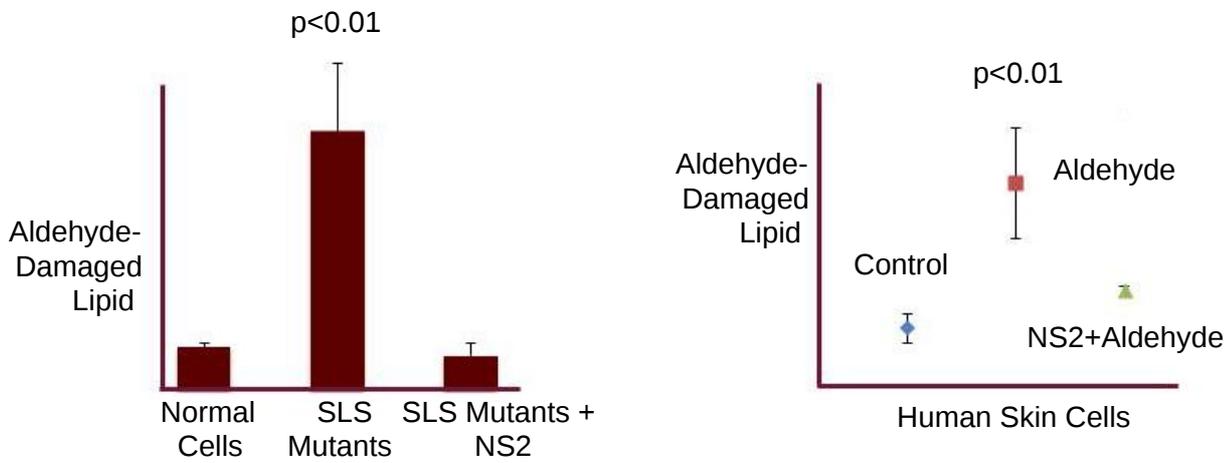
Single dose of NS2 has early and potent anti-inflammatory effect that reduces swelling in two different models of skin inflammation

NS2 Speeds Healing and Reduces Scarring of Lesions in Animal Models



NS2 speeds lesion healing and reduces scarring in a model of skin and eye disease

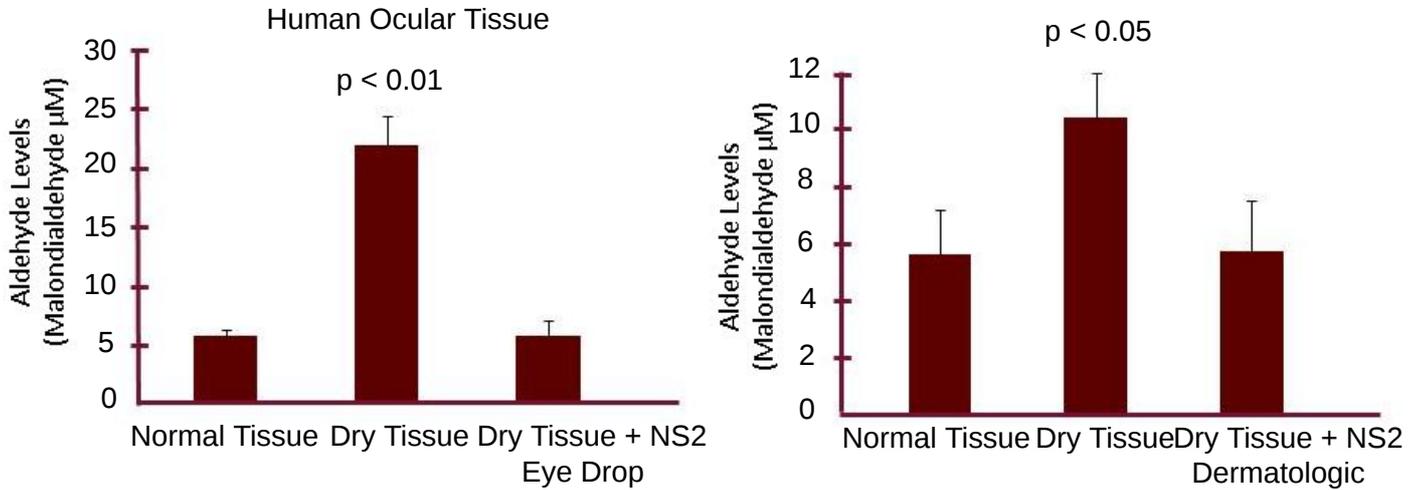
NS2 Protects a Key Lipid Relevant to Skin and Eye Disease in Cell Systems



NS2 prevents aldehyde-mediated damage of lipid that is critical to dermal moisture barrier and ocular tear integrity

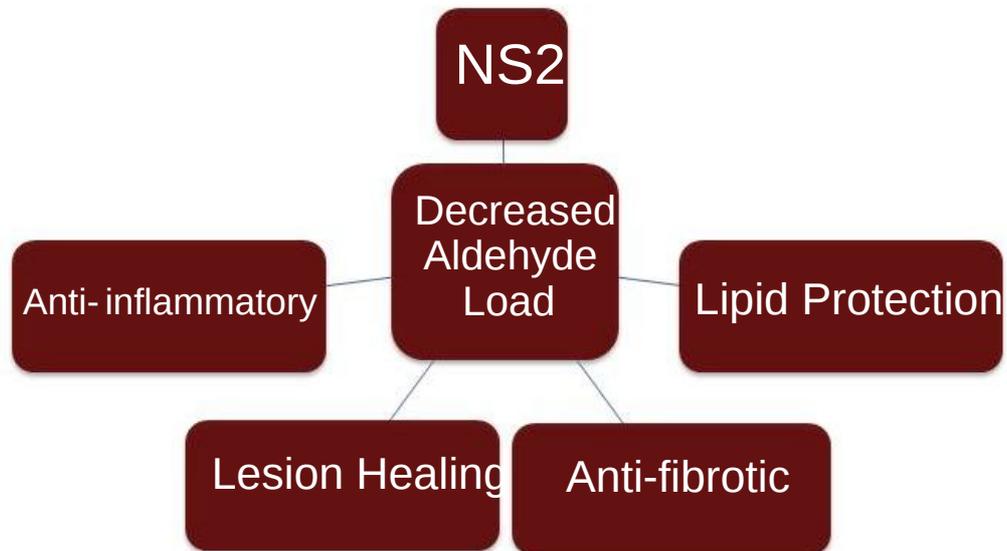
NS2 Traps Aldehydes Generated by Dry Conditions in Human Tissue

Malondialdehyde concentration in human tissues after 72 hours of NS2



Potential to reduce aldehyde-mediated damage in diseases characterized by dry tissue (Including Sjögren-Larsson Syndrome and Ocular Rosacea with Meibomian Gland Dysfunction)

NS2 Summary of Efficacy: Multiple Mechanisms of Action



The same biological mechanisms may apply to many orphan and prevalent dis

Positive NS2 Eye Drop Phase I Results

- o 48 healthy volunteers
- o Double-blinded and placebo controlled
- o Two treatment stages for two drug concentrations:
 - Single day 0.25% & 0.5% ~~bid~~
 - Seven day 0.25% & 0.5% *qid*
- o Eye drops were well tolerated in all treatment groups
- o No plasma exposure detected by LC-MS/MS (<5 ng/ml)

NS2 is Phase II-ready as an eye drop

Acute Anterior Uveitis: A Rare Inflammatory Ocular Disease

Uveitis



Acute anterior
ocular
inflammation

Pain,
photophobia,
loss of vision

Estimated
25,000 US
patients/year

Aldehydes are inflammatory mediators of ocular diseases, and can lead to degradation of tear quality

Anticipated Clinical Trial Designs for Ocular Disease

Acute Anterior Uveitis	
Formulation	Eye Drop
Control	Active 1:1:1
Total Patients	45 Patients
Treatment Time	8 weeks
Endpoints	Cell Counts, Symptoms

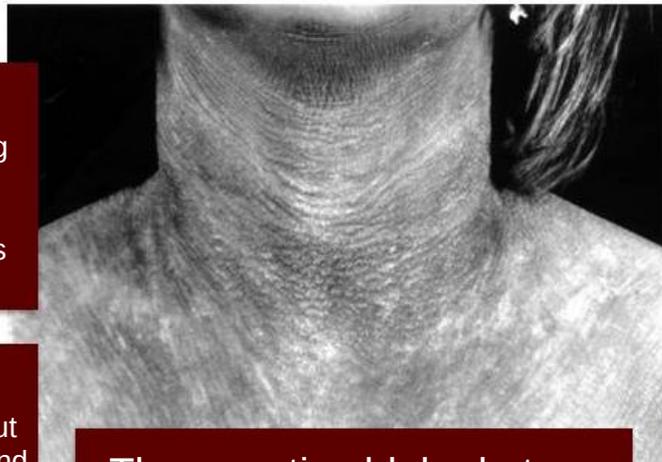
Sjögren-Larsson Syndrome (SLS): Orphan Disease with No Therapy

Orphan disease caused by mutation in Fatty Aldehyde Dehydrogenase, leading to high levels of toxic aldehydes

Symptoms include severe skin thickening (ichthyosis), retinal disease, and neurological disorders

Diagnosed at birth, but no approved therapy that addresses disease; patients survive into 50s

Estimated 0.4 births/100,000 = about 1000 patients in US and a greater number in Europe (1)



Therapeutic aldehyde trap would be analogous to an enzyme replacement therapy

(1) Extrapolating from a Swedish estimate, 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.

	Sjögren-Larsson Syndrome
Formulation	DermaTopical
Control	Placebo 1:1
Total Patients	12 Patients
Treatment Time	8 weeks
Endpoints	Visual Rating

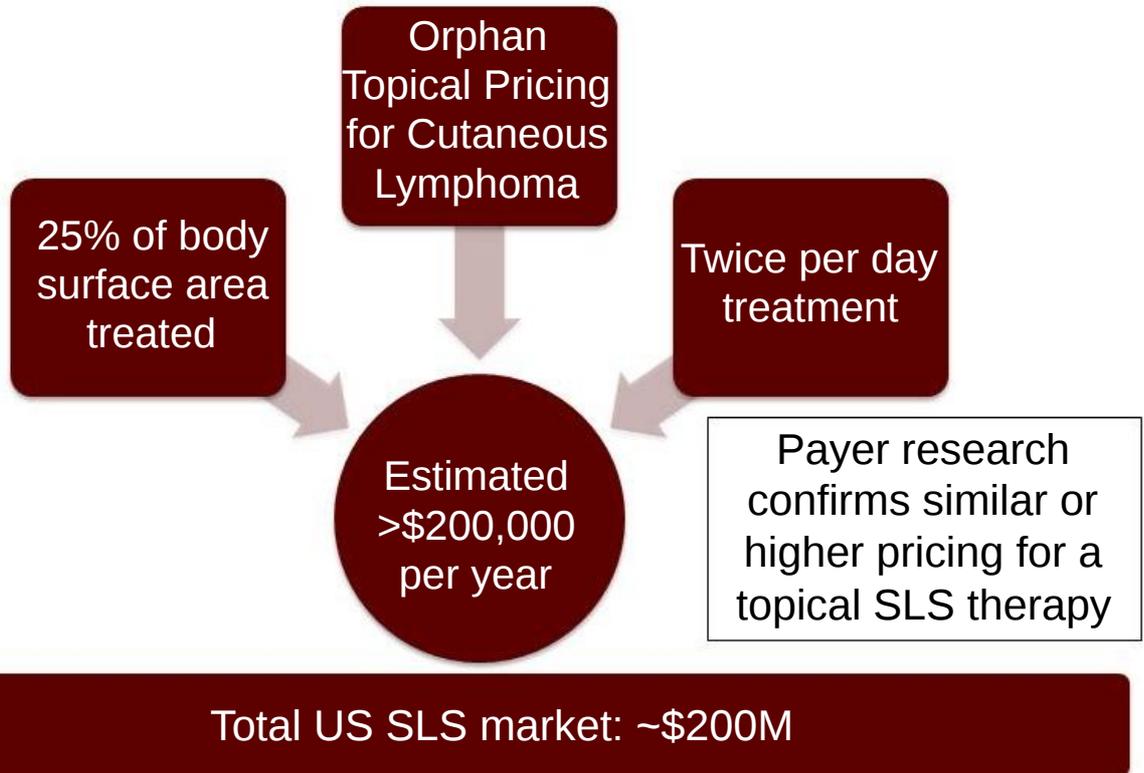
Unmet Medical Need for Our Clinical Indications

Market demand is substantial for a novel therapy that is safe and effective in the indications that we intend to develop

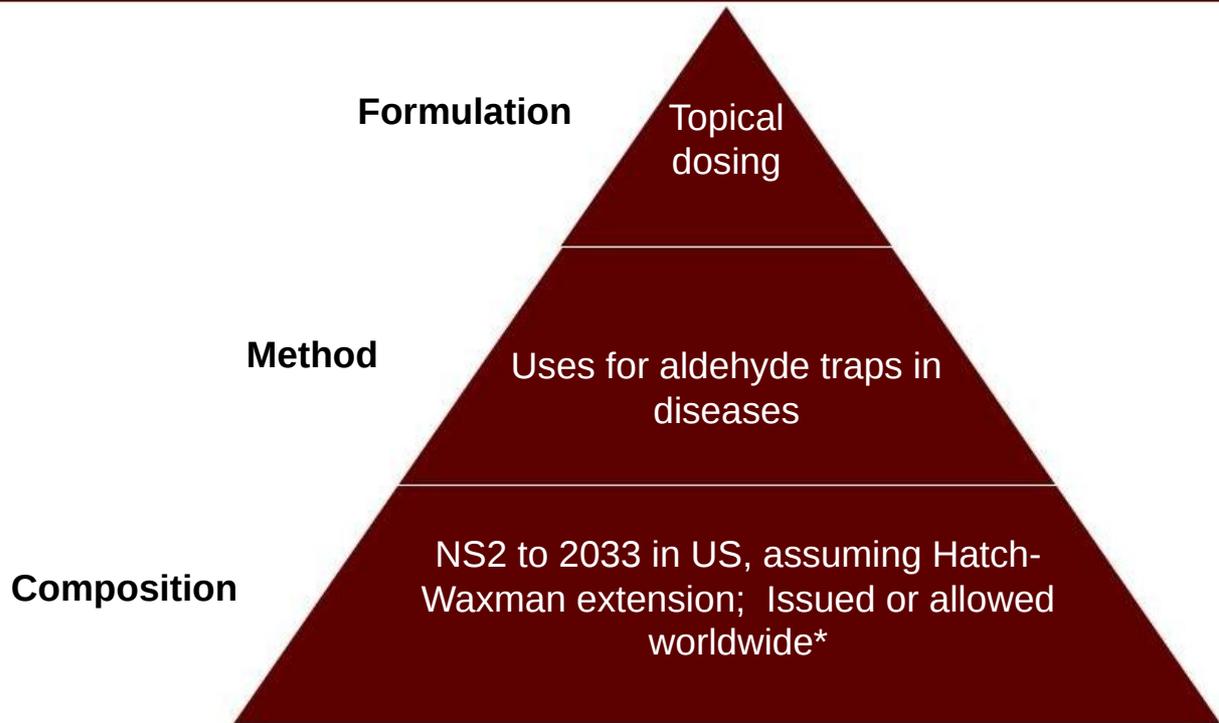
There is no FDA-approved therapy for Sjögren-Larsson Syndrome

Therapies for acute anterior uveitis are associated with significant side effects

Orphan Topical: Attractive Pricing, Large Market



Intellectual Property Portfolio: Composition of Matter into the 2030s



*Pending in Brazil, India

Orphan Disease Company Valuation Comparables

Company	Stage	Diseases in Phase II or III Clinical Trials	Valuation
Aldeyra Therapeutics (ALDX)	Phase II	2 ⁽¹⁾	\$23M
Bluebird Bio (BLUE)	Phase II	2	\$1.1B
Sarepta Therapeutics (SRPT)	Phase II	1	\$950M
Ultragenyx (RARE)	Phase II	2	\$1.7B
Synageva BioPharma (GEVA)	Phase III	1	\$2.6B
Intercept Pharmaceuticals (ICPT)	Phase III	4	\$6.4B

Orphan disease-focused biotechnology companies are highly valued, but Aldeyra has potential to expand to prevalent diseases as well.

(1) INDs anticipated by end of 2014, pending FDA review, among other contingencies.

- Closed IPO on May 7, 2014 raising gross proceeds of \$12M
- Proceeds from IPO to be used to complete two clinical trials and expected to provide working capital through 2015
- 2014 Society for Investigational Dermatology poster on novel treatment for dry skin and eye diseases selected for Late Breaking and Industry Review sessions
- Clinical development timelines remain on track
- Team expansion completed thru 2015

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- Extend to late 2020s worldwide and to 2033 in US, assuming Hatch-Waxman extension

Marquee Investors Validate Opportunity

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Aldeyra Therapeutics to Present at Upcoming Investor Conferences

Burlington, MA, September 5, 2014 Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to free aldehydes, today announced that Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, will present corporate overviews at the 16th Annual Rodman & Renshaw Global Investment Conference, taking place September 8, 2014 through September 10, 2014 in New York, New York, and the Aegis Capital Corporation 2014 Healthcare and Technology Conference, taking place on September 10, 2014 through September 13, 2014 in Las Vegas, Nevada.

Details of the presentations are as follows:

16th Annual Rodman & Renshaw Global Investment Conference

Date: **Wednesday, September 10, 2014**
Time: 10:00 a.m. ET
Place: The New York Palace Hotel (New York, NY)

Aegis Capital Corporation 2014 Healthcare and Technology Conference

Date: **Thursday, September 11, 2014**
Time: 1:30 p.m. PT
Place: Encore at Wynn Hotel (Las Vegas, NV)

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc., is a biotechnology company focused primarily on the development of products to treat diseases thought to be related to endogenous free aldehydes, a naturally occurring class of toxic molecules. The company has developed NS2 and other related compounds, designed to trap free aldehydes. Aldeyra plans to file Investigational New Drug (IND) applications for clinical testing of NS2 in 2014 for the treatment of Sjögren-Larsson Syndrome and acute anterior uveitis. NS2 has not been approved for sale in the U.S. or elsewhere. www.aldeyra.com

Investor Contact:

David Burke/Lee Roth
The Ruth Group
Tel: +1 646-536-7009/7012
dburke@theruthgroup.com/lroth@theruthgroup.com