# 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): May 3, 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**

**(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 2.02. Results of Operations and Financial Condition.**

On May 9, 2016, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release (the "Press Release") and is holding a conference call regarding its financial results for the quarter ended March 31, 2016. The Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are "forward-looking statements" under the securities laws, including, but not limited to, statements regarding Aldeyra's plans for its product candidates. 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," "target," "design," "estimate," "predict," "potential," "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; 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; 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 March 31, 2016, 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 conveyed on the conference call is provided only as of the date of the call, and Aldeyra undertakes no obligation to update any forward-looking statements presented on the call on account of new information, future events, or otherwise, except as required by law.

The information in Item 2.02 of this Current Report on Form 8-K and the Exhibit 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 5.02. Departure of Directors Or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On May 3, 2016, the Compensation Committee of the Board of Directors (the "Compensation Committee") of Aldeyra rescinded 50,000 shares of common stock from the stock option granted on March 16, 2016 to Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer. The number of shares of common stock initially covered by the March 16, 2016 option grant to Dr. Brady inadvertently exceeded the individual annual stock option limitation applicable to option awards under Aldeyra's 2013 Equity Incentive Plan (the "Plan"). The rescission of the 50,000 excess options brings the grant to Dr. Brady within the limitation of the Plan.

In addition, on May 2, 2016, the Compensation Committee awarded Dr. Brady a restricted stock unit award representing 27,096 shares of Aldeyra's common stock (the "RSU Award"). The RSU will vest ratably in equal annual installments over a four-year period beginning on May 3, 2017, provided that Dr. Brady has provided continuous service to Aldeyra through the applicable vesting date.

**Item 7.01. Regulation FD Disclosure.**

As reported under Item 8.01 of this Current Report on Form 8-K, Aldeyra also announced in the Press Release its randomized, parallel-group, investigator-masked, active-controlled Phase II clinical trial of NS2 ophthalmic solution in patients with noninfectious anterior uveitis demonstrated that NS2 was not statistically different from corticosteroid therapy in reducing inflammatory cell count in the anterior chamber of the eye. During a conference call referenced above, Aldeyra's management will discuss these top-line noninfectious anterior uveitis Phase II clinical trial results. A copy of the presentation being used in connection with this conference call is furnished herewith as Exhibit 99.2 and is incorporated by reference herein.

The 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 Exchange Act, or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 8.01. Other Events.**

On May 9, 2016, Aldeyra also announced in the Press Release that its randomized, parallel-group, investigator-masked, active-controlled Phase II clinical trial of NS2 ophthalmic solution in patients with noninfectious anterior uveitis demonstrated that NS2 was not statistically different from corticosteroid therapy in reducing inflammatory cell count in the anterior chamber of the eye.

The sections of the Press Release above the heading "Additional Recent Highlights" discussing the results of the Phase II clinical trial of NS2 are hereby incorporated by reference into this Current Report on Form 8-K.

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

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Aldeyra Therapeutics, Inc. Press Release dated May 9, 2016 |
| 99.2 | Aldeyra Therapeutics, Inc. Presentation dated May 9, 2016 |

**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: May 9, 2016

**EXHIBIT INDEX**

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|---|---|
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| 99.2 | Aldeyra Therapeutics, Inc. Presentation dated May 9, 2016 |


**Aldeyra Therapeutics Announces Positive Results From Phase II Clinical Trial in Subjects with Noninfectious Anterior Uveitis**

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*Company to Provide Corporate Update and First Quarter Financial Results*

*Announcement of the Second Positive Phase II Clinical Trial of NS2 in 2016*

*NS2 Has Now Demonstrated Clinical Activity in the Two Major Types of Ocular Inflammation*

LEXINGTON, Mass.— May 9, 2016 (MARKETWIRED) Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today reported that a randomized, multi-center, investigator-masked, comparator-controlled, parallel-group Phase II clinical trial of topical ocular NS2, a first-in-class aldehyde trap, demonstrated activity comparable to standard-of-care topical ocular corticosteroids in reducing anterior chamber cell count in patients with active noninfectious anterior uveitis.

Topical corticosteroids are often associated with ocular toxicity, including cataract formation and glaucoma (elevated intra-ocular pressure). The data released today suggest that NS2 has the potential to reduce or replace corticosteroid use in noninfectious anterior uveitis.

Commenting on the results, Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, said, “We are excited about these results, which, in combination with the positive data in allergic conjunctivitis that were released earlier this year, broaden the potential therapeutic applicability of topical ocular NS2 to many ocular inflammatory diseases. We look forward to continuing to develop aldehyde traps as a novel approach for the treatment of inflammation.”

Forty-five subjects were randomized equally to receive NS2 0.5% four times daily, Pred Forte® 1% (a corticosteroid) four times daily (tapered), or NS2 0.5% four times daily and Pred Forte® 1% twice daily (tapered). There were no statistical differences among all groups in any clinical endpoint, including anterior chamber cell count and ocular flare. NS2 was generally well tolerated and there were no serious adverse events, consistent with previous Phase I and Phase II clinical trials.

NS2 produced clinically meaningful effects on anterior chamber cell counts (ACC) comparable to corticosteroid. At the week 2 study visit, grade 0 (cell count of zero or one) ACC treatment response was seen in 33% of NS2 patients, 31% of Pred Forte® patients, and 31% of patients on combination therapy. At the week 8 study visit, grade 0 ACC treatment response was seen in 40% of NS2 patients, 46% of Pred Forte® patients, and 44% of patients on combination therapy. For ACC improvement of at least one grade, treatment response was seen in 53% of NS2 patients, 46% of Pred Forte® patients, and 50% of patients on combination therapy. For subjects that did not respond to therapy, rescue medication rates were similar between NS2 and Pred Forte®, with rescue medication required in 20% of NS2 patients, 38% of Pred Forte® patients and 25% of patients on combination therapy.

The principal investigator of the trial, Dr. Stephen Foster, a leading expert in ocular inflammation, has described this study outcome as “very encouraging with NS2 demonstrating clear activity in anterior uveitis and no evidence of significant adverse effects. This suggests that NS2 may be an important future treatment option for anterior uveitis patients. Effectiveness equal to topical corticosteroids with the absence of eye pressure elevation or cataract production would make this anti-inflammatory therapy an attractive therapeutic option for treating uveitis.”

Aldehydes are thought to mediate both major forms of inflammation, allergy (such as allergic conjunctivitis) and autoimmune disease (such as noninfectious anterior uveitis). In February 2016, Aldeyra reported positive Phase II data with topical ocular NS2 in allergic conjunctivitis. The Phase II results in noninfectious anterior uveitis released today suggest that NS2 is also active in autoimmune disease.

**Additional Recent Highlights**

- **Reported positive results from Phase II clinical trial in subjects with allergic conjunctivitis.** Aldeyra reported that the results of a randomized, parallel-group, single-center, double-masked, vehicle-controlled Phase II clinical trial of topical ocular NS2 in subjects with induced allergic conjunctivitis demonstrated statistically significant and sustained activity of NS2 over vehicle in reducing ocular itching and tearing. NS2 was generally well tolerated and there were no serious adverse events during the trial.
- **Phase II clinical data in Sjögren-Larsson Syndrome expected in third quarter of 2016.** Aldeyra confirmed that the results of a Phase II clinical trial of dermatologic NS2 for the treatment of ichthyosis in Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism, are expected in the third quarter of 2016.
- **Hired key employees for pipeline advancement**. In January 2016, Aldeyra hired David J. Clark, M.D. as Chief Medical Officer. Dr. Clark has 18 years of drug development experience at Pfizer, SmithKline Beecham, and several biotechnology companies focused on rare and common diseases. Aldeyra also hired Mary Taylor, MPH as the Senior Vice President, Regulatory Affairs in February 2016. Ms. Taylor’s industry experience spans over 30 years in drug development and senior regulatory positions at Shire, Bayer, and multiple biotechnology companies. The additions of Dr. Clark and Ms. Taylor enhance the ability to advance multiple treatments through the clinic and to the market for a number of inflammatory diseases and inborn errors of aldehyde metabolism.

**First Quarter 2016 Financial Review**

For the quarter ended March 31, 2016, Aldeyra reported a net loss of approximately $(5.0) million compared to a net loss of approximately $(2.1) million for the quarter ended March 31, 2015. Basic and diluted net loss per share was $(0.51) for the quarter ended March 31, 2016 compared to basic and diluted net loss of $(0.32) per share for the quarter ended March 31, 2015. Losses have resulted from the costs of our clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were approximately $3.5 million for the quarter ended March 31, 2016 compared to approximately $1.1 million for the quarter ended March 31, 2015. The increase of approximately $2.4 million is primarily related to the increase in our external research and development expenditures, including preclinical, manufacturing and clinical efforts and an increase in personnel costs including stock based compensation due to an increase in headcount.

General and administrative expenses were approximately $1.5 million for the quarter ended March 31, 2016, compared to approximately $972,000 for the quarter ended March 31, 2015. The increase was primarily related to an increase in insurance costs, legal costs and personnel costs, including stock-based compensation due to an increase in headcount.

Cash, cash equivalents and marketable securities were $23.0 million at March 31, 2016.

**Conference Call and Webcast Information**

The Company will hold a conference call on Monday, May 9, 2016 at 8:00 a.m. EDT to discuss the results and operational updates. The dial-in numbers are 1-888-438-5519 for domestic callers and 1-719-325-2308 for international callers. The conference ID number for both is 4012631. A live webcast of the conference call will also be available on the investor relations page of the Aldeyra Therapeutics corporate website at www.aldeyra.com.

After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for one year. In addition, a telephonic replay of the call will be available until May 9, 2017. The replay dial-in numbers are 1-888-203-1112 for domestic callers and 1-719-457-0820 for international callers. Please use event passcode 4012631.

**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. The company's lead product, NS2, 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. For more information regarding our novel therapeutic approaches, please visit www.aldeyra.com.

**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 Sjögren-Larsson Syndrome**

Sjögren-Larsson Syndrome is a rare disease caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There is no FDA-approved therapy for SLS.

**Safe Harbor Statement**

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's plans for its product candidates and its financial guidance. 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; 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, 2015 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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 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.

**ALDEYRA THERAPEUTICS, INC.**
**BALANCE SHEETS**

| | March 31, 2016 | December 31, 2015 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,148,524 | $ 14,648,866 |
| Marketable securities | 12,877,281 | 12,941,776 |
| Prepaid expenses and other current assets | 283,509 | 497,552 |
| Total current assets | 23,309,314 | 28,088,194 |
| Deferred offering costs | 45,986 | 36,236 |
| Fixed assets, net | 81,466 | 80,334 |
| Total assets | $ 23,436,766 | $ 28,204,764 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 578,017 | $ 851,160 |
| Accrued expenses | 1,035,888 | 1,186,429 |
| Current portion of credit facility | 193,866 | 77,546 |
| Total current liabilities | 1,807,771 | 2,115,135 |
| Credit facility, net of current portion and debt discount | 1,101,968 | 1,211,310 |
| Total liabilities | 2,909,739 | 3,326,445 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding | — | — |
| Common stock, voting, $0.001 par value; 150,000,000 authorized and 9,712,521 shares issued and outstanding, respectively | 9,713 | 9,713 |
| Additional paid-in capital | 84,084,750 | 83,478,851 |
| Accumulated other comprehensive income (loss), net of tax | 1,800 | (8,361) |
| Accumulated deficit | (63,569,236) | (58,601,884) |
| Total stockholders' equity | 20,527,027 | 24,878,319 |
| Total liabilities and stockholders' equity | $ 23,436,766 | $ 28,204,764 |

**ALDEYRA THERAPEUTICS, INC.**
**STATEMENT OF OPERATIONS**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2016 | 2015 |
| Operating expenses: | | |
| Research and development | $ 3,511,477 | $ 1,136,434 |
| General and administrative | 1,455,559 | 972,101 |
| Loss from operations | (4,967,036) | (2,108,535) |
| Other income (expense): | | |
| Interest income | 24,719 | — |
| Interest expense | (25,035) | (28,024) |
| Total other income (expense), net | (316) | (28,024) |
| Net loss | $ (4,967,352) | $ (2,136,559) |
| Net loss per share: | | |
| Basic | $ (0.51) | $ (0.32) |
| Diluted | $ (0.51) | $ (0.32) |
| Weighted average common shares outstanding: | | |
| Basic | 9,712,521 | 6,667,519 |
| Diluted | 9,712,521 | 6,667,519 |

Corporate Contact:

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stulipano@aldeyra.com

Investor Contact:

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


# *Noninfectious Anterior Uveitis Phase II Results and Ocular Clinical Development Update*

May 9, 2016

# Disclaimers and Forward-Looking Statements

- This presentation contains 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 and expenses, business strategies and plans, research and development plans or expectations, trends, market sizing, competitive position, 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. 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 commencement, enrollment and completion of Aldeyra's clinical trials; 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 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 its expenses and revenue, the sufficiency or use 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, 2015 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov.
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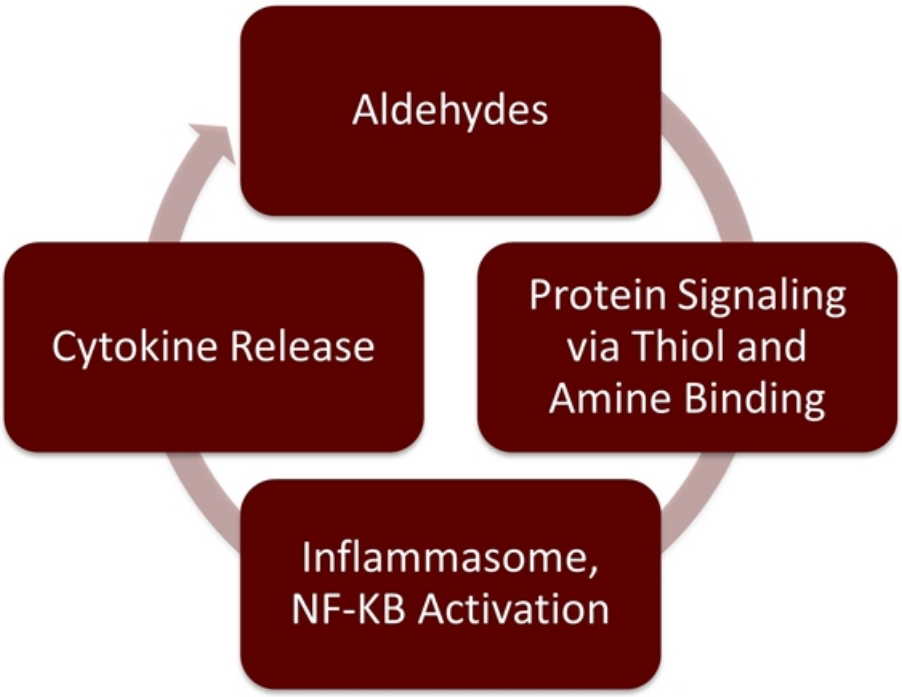
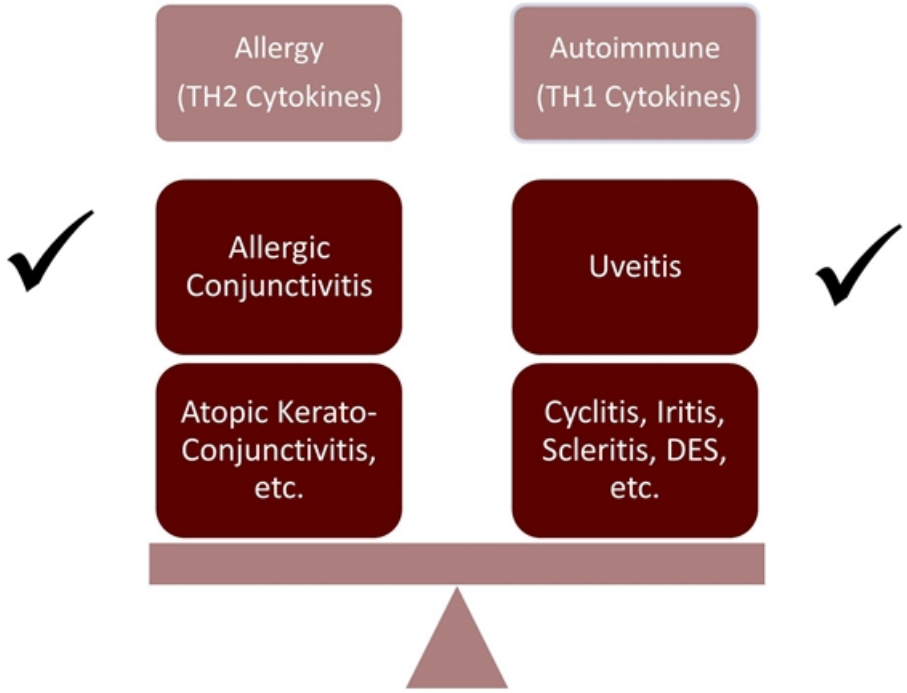
# Aldehydes Are Mediators of Inflammation




NS2 is a first-in-class aldehyde trap and is the lead compound in a novel anti-inflammatory platform.

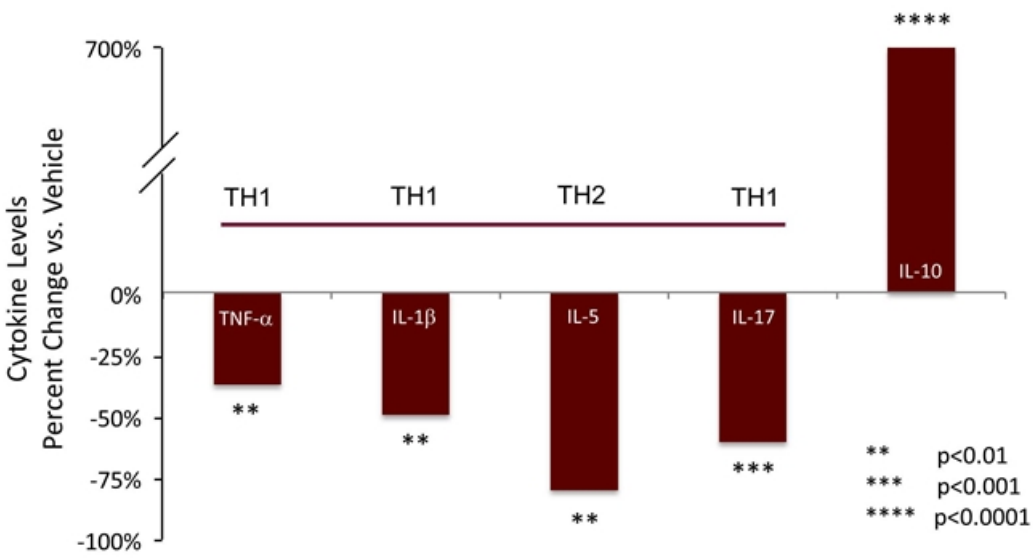
# The Aldehyde Trap Ocular Anti-Inflammatory Platform




NS2 has demonstrated activity in the two major types of inflammation, and has the potential to be efficacious in a wide variety of inflammatory disease.

# Trapping Aldehydes Generates a Broad Anti-Inflammatory Response

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

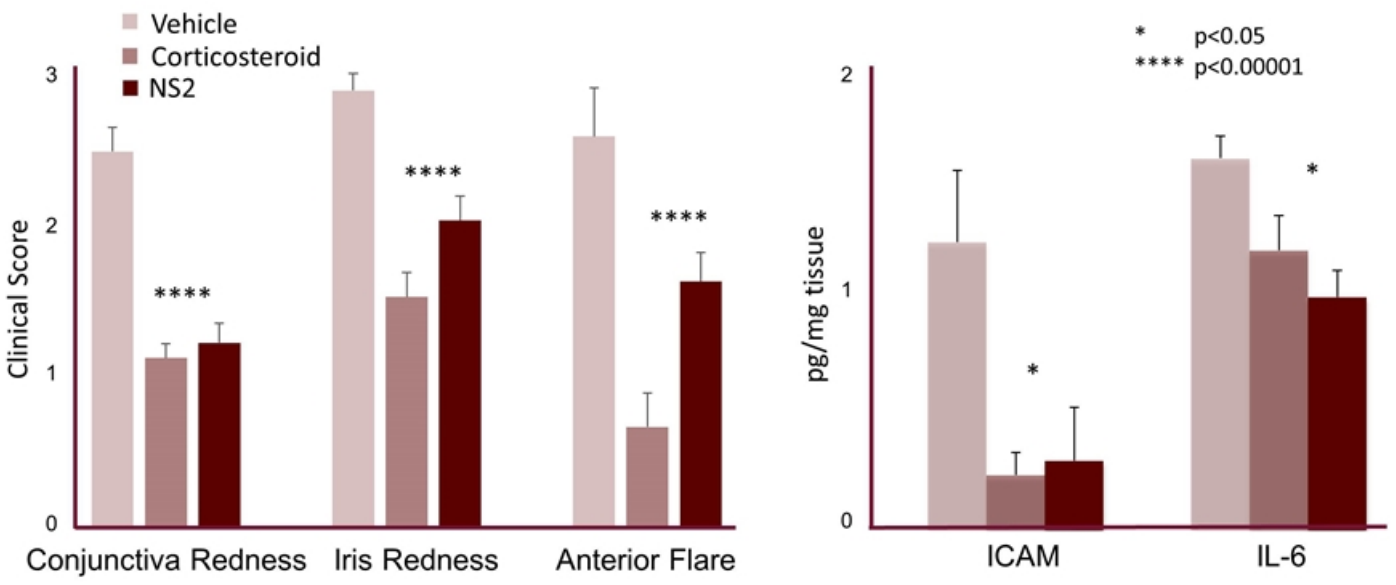



In a murine model of cytokine storm, NS2 administration significantly reduced levels of pro-inflammatory cytokines while up-regulating an anti-inflammatory cytokine.

Data presented at the American Academy of Asthma Allergy and Immunology 2015 Annual Meeting

# Topical NS2 Decreases Ocular Inflammation in an Animal Model

Rat LPS-Induced Ocular Inflammation at 24 Hours Post-Stimulus, NS2 dosed topically QID



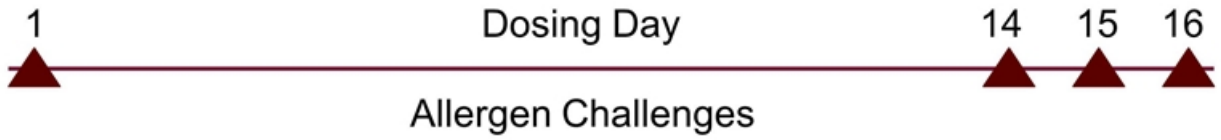

Topically administered NS2 has clinically significant effects in a widely used animal model of ocular inflammation and compares favorably to corticosteroids.

Data presented at the Association for Research in Vision and Ophthalmology 2015 Annual Meeting

# Phase II Clinical Trial Design for Allergic Conjunctivitis

## Allergic Conjunctivitis

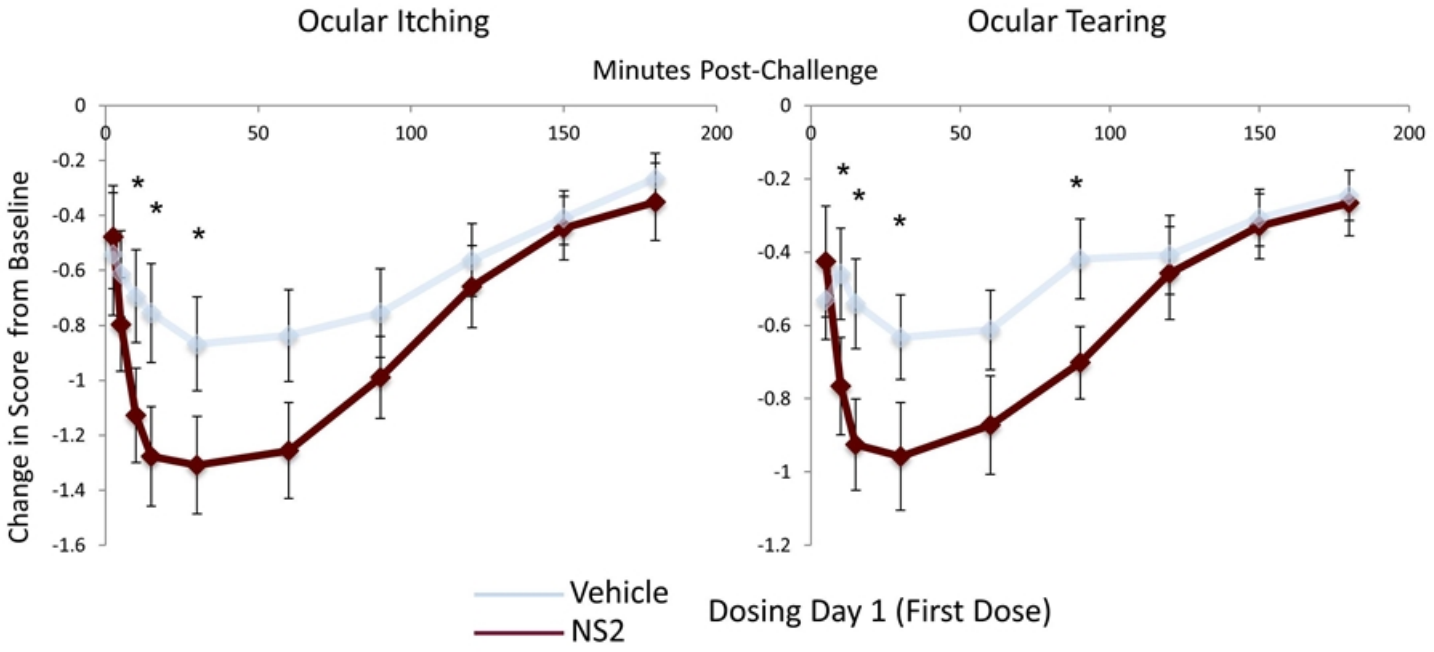
| | |
|---|---|
| **Dosing** | NS2 Topical Ocular QID |
| **Control** | Vehicle 1:1, Double-Masked |
| **Enrollment** | 100 Patients |
| **Treatment Time** | 16 Days |
| **Endpoints** | Itching/tearing scores, redness |




Allergen Challenges

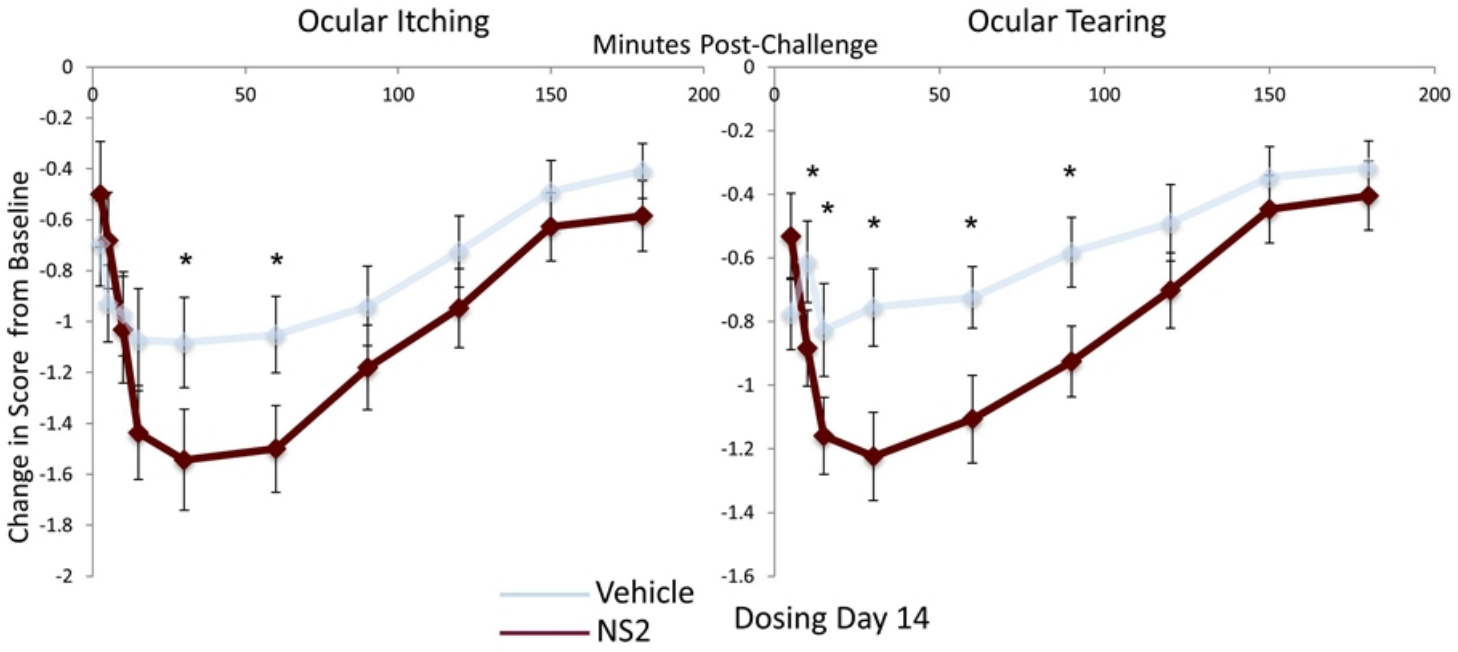
Further information can be found on www.clinicaltrials.gov: Trial #NCT02578914.

# Clinically Meaningful Effects Observed in Allergic Conjunctivitis Phase II



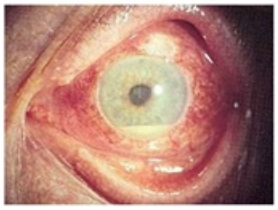

NS2 achieved reductions in ocular itching and tearing that were clinically relevant and statistically greater than vehicle.

# Clinically Meaningful Effects Observed in Allergic Conjunctivitis Phase II




NS2 achieved reductions in ocular itching and tearing that were clinically relevant and statistically greater than vehicle.

# Noninfectious Anterior Uveitis: A Serious Inflammatory Disease



## Uveitis

- Acute anterior ocular inflammation
- Inflammatory cells in front of eye, pain, photophobia, loss of vision
- Estimated 25,000 US patients/year
- Currently treated with corticosteroids, which may lead to cataracts and glaucoma

Aldeyra's lead aldehyde trap reduced anterior chamber cell count in a manner comparable to corticosteroids in a Phase II clinical trial Q2 2016.

# Noninfectious Anterior Uveitis Phase II Clinical Design

| | |
|---|---|
| **Dosing** | NS2 0.5% Topical Ocular<br>Pred Forte® 1% Topical Ocular |
| **Randomization** | Active-Controlled 1:1:1<br>NS2 QID, Pred Forte® QID Taper, NS2 QID + Pred Forte® BID Taper |
| **Enrollment** | 45 Patients with Active Disease |
| **Treatment Time** | 6 Weeks |
| **Endpoints** | Cell Count, Flare, Symptoms |

Further information can be found on www.clinicaltrials.gov: Trial #NCT02406209.

# NS2 Comparable to Corticosteroid in Noninfectious Anterior Uveitis Phase II

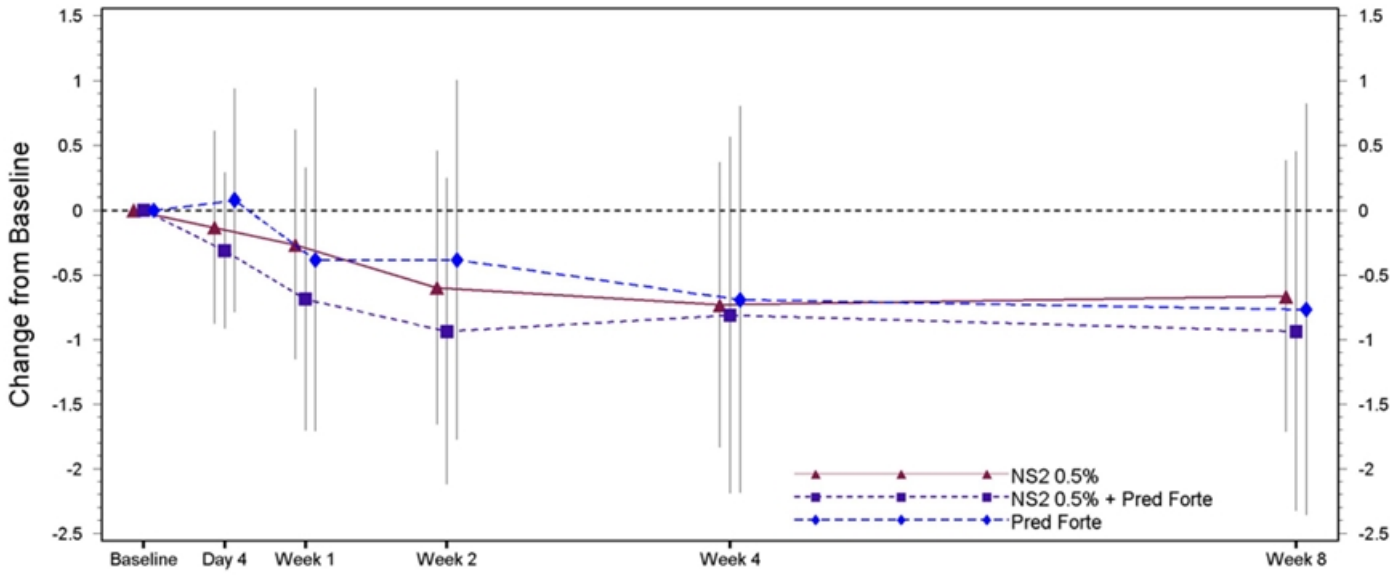
| | NS2 (n=15) | Pred Forte (n=13) | NS2 + Pred Forte (n=16) |
|---|---|---|---|
| Week 2 Cell Grade 0 | 5 (33%) | 4 (31%) | 5 (31%) |
| Week 8 Cell Grade 0 | 6 (40%) | 6 (46%) | 7 (44%) |
| ≥ 1 Cell Grade Reduction | 8 (53%) | 6 (46%) | 8 (50%) |
| Rescue Medication Required | 3 (20%) | 5 (38%) | 4 (25%) |

Notes:

- Grade 0 = cell count of zero or one in anterior chamber
- Patients were rescued at investigator discretion if no improvement or worsening of cell count

# NS2 Comparable to Corticosteroid in Noninfectious Anterior Uveitis Phase II

Mean (+/-SD) Change from Baseline in Anterior Chamber Cell Count over Time
(mITT Population*, Last Observation Carried Forward)




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

# NS2 Comparable to Corticosteroid in Noninfectious Anterior Uveitis Phase II

No statistically significant differences* for anterior chamber cell count or flare were observed between groups in:

- Time to sustained grade of 0
- Proportion of subjects with sustained grade 0
- Time to sustained reduction of 1-point or greater grade
- Proportion of subjects with sustained 1-point or greater reduction of grade

*Trial not statistically powered.

# NS2 Generally Well-Tolerated in Noninfectious Anterior Uveitis Phase II

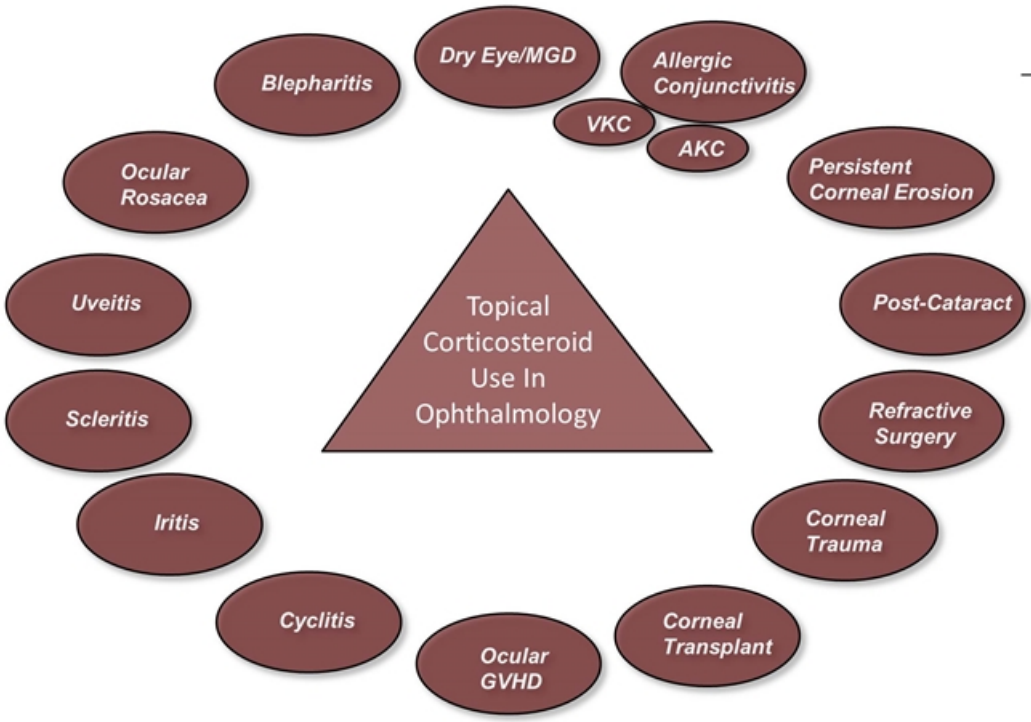
- No significant differences observed in symptom scores
- No SAEs in any group
- Eye stinging/burning was reported in the NS2 treated groups
  - 4 subjects in NS2 group, leading to one discontinuation
  - 3 subjects in NS2+Corticosteroid group, leading to one discontinuation
- Overall, NS2 was well tolerated with no safety issues raised for future studies of topical ocular NS2

# Clinical/Regulatory Development Plans for Topical Ocular NS2

**All Development Plans Are Contingent on FDA Interaction**

- Allergic Conjunctivitis
  - Pre-IND Meeting and IND Filing (prior Phase II was under CTA)
  - Phase II/III Dose-Ranging
- Noninfectious Anterior Uveitis
  - Regulatory Advice Meeting
  - Phase II/III Dose-Ranging
- Other ocular inflammation Phase II trials under review, both in rare and common diseases

# Potential Markets for NS2 in Ocular Inflammation




**Price Benchmarks**

| Drug | Retail Price Point |
|---|---|
| Restasis | $400 - $500 (per month) |
| Lotemax, Durazol, Patanol, Pataday, Pred Forte 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