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): February 29, 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 Disclosure.

As reported under Item 8.01 of this Current Report on Form 8-K, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release announcing positive top-line results from its Phase IIa clinical trial of NS2 for the treatment of allergic conjunctivitis. During a conference call scheduled to be held at 8:00 a.m. Eastern Time on February 29, 2016, Aldeyra's management will discuss the top-line allergic conjunctivitis Phase 2 clinical trial results.

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 Securities 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 February 29, 2016, Aldeyra issued a press release announcing that its Phase IIa clinical trial of NS2 for the treatment of allergic conjunctivitis achieved statistically significant effect over vehicle in a randomized, parallel, single center, double masked, vehicle controlled trial. The purpose of the trial was to determine the activity and safety of NS2 in patients with grass, tree or ragweed-pollen induced seasonal allergic conjunctivitis. In addition, Aldeyra also provided an update regarding the status of its ongoing noninfectious anterior uveitis Phase II clinical trial. A copy of Aldeyra's press release is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated February 29, 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: February 29, 2016

February 29, 2016

Aldeyra Therapeutics Reports Positive Results from Phase IIa Clinical Trial in Subjects with Allergic Conjunctivitis

NS2 Demonstrates Statistically Significant and Sustained Clinical Effects

Data Suggest Aldehyde Trapping as Novel Approach for the Treatment of Inflammatory Diseases

Conference Call to Be Held Today at 8:00 am ET

LEXINGTON, Mass., February 29, 2016 (GLOBE NEWSWIRE) -- Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today reported that the results of a randomized, parallel-group, single-center, double-masked, vehicle-controlled Phase IIa clinical trial of topical ocular NS2 in subjects with induced allergic conjunctivitis demonstrated statistically significant activity of NS2 over vehicle in reducing ocular itching and tearing.

Aldehydes are thought to be related to inflammatory conditions including allergic conjunctivitis, as well as other forms of ocular and non-ocular inflammation. NS2, a small molecule aldehyde trap, was tested in a conjunctival allergen provocation test (CAPT) model of allergic conjunctivitis. One hundred healthy men and women with at least a two-year history of allergic conjunctivitis to grass, tree or ragweed pollen were enrolled and randomized in equal groups for treatment with topical ocular NS2 or vehicle. The clinical endpoints in the trial included patient assessment (on a 0 to 4 point scale) of ocular itching and tearing, two prominent inflammation-related symptoms of allergic conjunctivitis.

Statistically significant differences were demonstrated for ocular itching ($p<0.05$) and ocular tearing ($p<0.05$) between NS2 and vehicle after single dose and multiple dose administration. NS2 demonstrated durable effects throughout the three hours following CAPT challenge. The effects of NS2 persisted across substantially all time points for all CAPT challenges despite a stronger than expected vehicle effect. The reductions from baseline scores were of the same magnitude seen in the CAPT model with existing therapies utilized in the treatment of allergic conjunctivitis, and peak changes exceeded one point for both ocular itching and ocular tearing scores.

NS2 was generally well tolerated and there were no safety concerns during the trial. Transient and generally mild stinging was noted in the treatment arm. Two patients dropped out of the trial during treatment.

Commenting on the results, Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, said, “To our knowledge, the data from this clinical trial represent the first example of clinical efficacy of an aldehyde trap in human disease. We are thrilled with the outcome of this trial and believe that the results suggest important insight into the physiology of inflammation and further applicability of aldehyde trapping in the treatment of inflammatory disease.”

Aldeyra is also performing a Phase II clinical trial of topical ocular NS2 in patients with noninfectious anterior uveitis, and a Phase II trial of dermatologic NS2 in patients with Sjögren-Larsson Syndrome. The last visit for the last patient in the noninfectious anterior uveitis Phase II clinical trial occurred this month, and data from the trial are expected in the second quarter of 2016.

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Conference Call

Aldeyra will hold a conference call on February 29, 2016 at 8:00 a.m. ET. Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer; David J. Clark, M.D., Chief Medical Officer; and Stephen Tulipano, Chief Financial Officer, will host a conference call to discuss results of the clinical trial. The dial-in numbers are 1-877-407-0784 for domestic callers and 1-201-689-8560 for international callers. The conference ID number for both is 13631657. A live webcast of the conference call will also be available on the investor relations page of Aldeyra's corporate website at www.aldeyra.com.

After the live webcast, the event will remain archived on Aldeyra's website for 60 days. In addition, a telephonic replay of the call will be available until March 7, 2016. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 13631657.

About NS2

NS2 is an aldehyde-binding small molecule based on an innovative platform technology focused on trapping aldehydes, which are toxic and pro-inflammatory mediators of numerous diseases. By decreasing aldehyde load, NS2 may mitigate excessive inflammation and address diseases where aldehyde metabolism is impaired, including certain inborn errors of metabolism.

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 excessive tear production in addition to ocular itching, swelling, and redness.

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 aldehydes, a naturally occurring class of toxic molecules. The company has developed NS2, a product candidate designed to trap aldehydes. Aldeyra has completed Phase IIa testing of NS2 in subjects with induced allergic conjunctivitis, and has initiated clinical testing of NS2 for the treatment of Sjögren-Larsson Syndrome and noninfectious anterior uveitis. NS2 has not been approved for sale in the U.S. or elsewhere. www.aldeyra.com

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 the development of NS2 and timing of the results from Aldeyra's noninfectious anterior uveitis Phase II clinical trial. 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, 2014 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, 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 described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2015, to be filed with the SEC in the first 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.

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