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): December 18, 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.)

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)

Dere-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 8.01. Other Events.

On December 18, 2014, Aldeyra Therapeutics, Inc. issued a press release announcing that it has submitted an Investigational New Drug application to the United States Food and Drug Administration to conduct Phase 2 clinical testing of NS2 for the treatment of noninfectious anterior uveitis.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|----------------|--|
| 99.1 | Press Release of Aldeyra Therapeutics, Inc. dated December 18, 2014. |

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: December 18, 2014



Aldeyra Therapeutics Submits FDA IND Filing for Noninfectious Anterior Uveitis

Lexington, MA, December 18, 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 an Investigational New Drug application (IND) to conduct Phase 2 clinical testing of NS2 for the treatment of noninfectious anterior uveitis, was submitted to the United States Food and Drug Administration (FDA) on December 16, 2014.

Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, commented, "The submission of an IND for NS2 in the treatment of noninfectious anterior uveitis is a major milestone for Aldeyra and is another step forward in the execution of our development strategy. NS2 has the potential to reduce or eliminate the use of steroids in the treatment of this disease, which we believe would significantly enhance the treatment options for these patients and improve their long-term ocular health. We remain focused on advancing NS2 through its planned clinical program as we prepare to initiate the Phase 2 trial early next year."

Noninfectious anterior uveitis is a rare disease that affects an estimated 25,000 patients per year in the United States. Aldeyra has developed an ophthalmic formulation of its lead product candidate, NS2, to treat this disease and intends to initiate a Phase 2 trial for this indication in 2015, pending FDA review of the IND. Noninfectious anterior uveitis is characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia. High levels of proinflammatory free aldehydes are associated with this and other ocular and systemic diseases. By trapping free aldehydes, NS2 may reduce inflammation, fibrosis and tissue damage associated with inflammatory ocular diseases. Furthermore, there is a need for safe and effective alternatives to corticosteroids for noninfectious anterior uveitis and other forms of ocular inflammation.

About NS2

NS2, a product candidate that is designed to trap free aldehydes, is under development for the treatment of noninfectious anterior uveitis, a rare disease characterized by severe inflammation and pain in the anterior eye and Sjögren-Larsson Syndrome (SLS), a rare disease caused by mutations in an enzyme that metabolizes fatty aldehydes.

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, a product candidate designed to trap free aldehydes. Aldeyra plans to initiate a Phase II clinical study of NS2 in noninfectious anterior uveitis in early 2015 and file an Investigational New Drug application in 2014 for clinical testing of NS2 in Sjögren-Larsson Syndrome. 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. 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 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; Aldeyra's ability to attract or retain key personnel; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at <u>www.sec.gov</u>.

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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