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): January 25, 2017

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 8.01 Other Events.

On January 25, 2017, Aldeyra Therapeutics, Inc. (“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 99.1 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	Press Release of Aldeyra Therapeutics, Inc. dated January 25, 2017.

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: January 25, 2017

Exhibit 99.1

Aldeyra Therapeutics Announces Clinical Development Update for Phase 3 Programs

- Noninfectious Anterior Uveitis: Enrollment of first-ever vehicle-controlled Phase 3 clinical trial is expected to begin in the second quarter of 2017.
- Sjögren-Larsson Syndrome: Enrollment of first-ever Phase 3 clinical trial is expected to begin in the second half of 2017.

Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today provided an update on its Phase 3 clinical programs in noninfectious anterior uveitis and Sjögren-Larsson Syndrome.

Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra, commented, “Following recent meetings with the FDA, we are pleased to update the progress of our late-stage clinical programs, as we continue to advance our novel aldehyde trap platform. Consistent with prior guidance, we anticipate initiation of our Phase 3 clinical trial in noninfectious anterior uveitis in the second quarter of 2017, and initiation of our Phase 3 clinical trial in Sjögren-Larsson Syndrome in the second half of this year.”

Noninfectious Anterior Uveitis

Based on meetings held with the U.S. Food and Drug Administration (FDA) in 2016 and 2017, Aldeyra expects to initiate enrollment, in the second quarter of 2017, of the first-ever vehicle-controlled Phase 3 clinical trial in noninfectious anterior uveitis (NAU). The trial is expected to enroll up to 100 patients, randomized equally to topical ocular ADX-102 or vehicle treatment for four weeks. Consistent with other NAU clinical trials, the primary endpoint is the clearing of inflammatory cells in the anterior chamber of the eye. Data from the trial are expected in late 2018.

NAU is a rare and serious ocular disorder that can lead to blindness, and is often treated with corticosteroids, which can lead to significant ocular toxicities, including cataracts, elevation of intraocular pressure and glaucoma, and infection. In May 2016, Aldeyra announced Phase 2 data demonstrating that ADX-102, Aldeyra’s lead compound, was at least as effective as a corticosteroid in treating NAU. Importantly, ADX-102 did not lead to the elevation of intraocular pressure observed in the corticosteroid group of patients.

Sjögren-Larsson Syndrome

Based on an End of Phase 2 meeting with the FDA, Aldeyra plans to initiate enrollment, in the second half of 2017, of the first-ever Phase 3 clinical trial in Sjögren-Larsson Syndrome (SLS). The proposed clinical trial is expected to enroll up to 30 SLS patients in the United States and Europe. All patients will be treated with topical dermal ADX-102 for at least four months. The primary endpoint will be the severity of the dermatologic disease. Data from the trial are expected in 2019.

SLS is a rare genetic condition characterized in part by ichthyosis, a serious dermatologic condition that causes significant morbidity, including bleeding and social stigma. There are no FDA-approved therapies indicated for the treatment of SLS. In August 2016, Aldeyra announced Phase 2 data demonstrating that topical dermal ADX-102 was statistically superior to vehicle in improving ichthyosis in SLS patients.

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.

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 expected development timelines. 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 September 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 Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the SEC in the first quarter of 2017. All of Aldeyra's development timelines could be subject to adjustment depending on recruitment rate, regulatory agency review, and other factors that could delay the initiation and completion of clinical trials.

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.