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 24, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market, LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01. Other Events.

On September 24, 2019, Aldeyra Therapeutics, Inc. issued a press release attached hereto as Exhibit 99.1 and incorporated by reference herein announcing that the U.S. Food and Drug Administration has granted fast track designation to ADX-2191 for the prevention of proliferative vitreoretinopathy.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated September 24, 2019.

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.

Dated: September 24, 2019

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed
Name: Joshua Reed
Title: Chief Financial Officer

Exhibit 99.1

News Release

Aldeyra Therapeutics Receives Fast Track Designation for ADX-2191 for the Prevention of Proliferative Vitreoretinopathy

Lexington, Mass., September 24, 2019 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), today announced that the U.S. Food and Drug Administration (FDA) has granted fast track designation to ADX-2191 for the prevention of proliferative vitreoretinopathy (PVR). PVR is a serious, sight-threatening condition with no approved treatment.

“Fast track designation is an important milestone for our retinal disease platform, and promising news for PVR patients,” said Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “The FDA’s decision underscores the potential of ADX-2191 to prevent this devastating condition and creates the framework for ADX-2191 to reach the market promptly if approved.”

PVR, a rare inflammatory disorder of the retina that leads to severe retinal scarring and blindness, occurs most commonly following retinal detachment repair surgery or ocular injury. More than 50% of PVR cases result in severe uncorrectable vision loss, and 76% of PVR patients suffer from at least moderate uncorrectable vision loss.

Aldeyra expects to initiate its adaptive Phase 3 GUARD Trial of ADX-2191 for the prevention of PVR in the fourth quarter of 2019. The trial will compare recurrence rates of PVR-related retinal detachment across patients treated with ADX-2191 or standard of care following surgical repair of retinal detachment.

The fast track designation is designed to facilitate the development and expedite the review of drugs that treat serious conditions, potentially accelerating patient access to new therapies.

“Fast track designation enables us to engage in more frequent communications with the FDA to discuss our development plan for ADX-2191, and provides eligibility for Priority Review and rolling New Drug Application submission,” said David J. Clark, M.D., Chief Medical Officer of Aldeyra. “We look forward to working with the FDA as we advance ADX-2191 into Phase 3 development.”

About ADX-2191

ADX-2191, an intravitreal formulation of methotrexate, has been granted orphan drug designation for the prevention of proliferative vitreoretinopathy (PVR). The observed clinical activity of ADX-2191 in patients with PVR is believed to be the result of down-regulation of aberrant retinal cell proliferation and activity, thereby leading to reduced retinal scarring that is characteristic of PVR. Aldeyra retains an exclusive license to certain patents related to the use of ADX-2191 for the prevention of PVR.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are first-in-class potential treatments in development for dry eye disease, allergic conjunctivitis, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's plans and expectations for the clinical development and commercialization of ADX-2191 for the prevention of PVR. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. 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," "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. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials. 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; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the

ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving Aldeyra's product candidates; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) Aldeyra's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's 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 limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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.

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