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 24, 2020

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 February 24, 2020, in connection with its 2020 Research & Development Day, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release that provided an update on Aldeyra's late-stage clinical development pipeline. 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 February 24, 2020.

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

Dated: February 24, 2020

Aldeyra Therapeutics to Provide Update on Late-Stage Clinical Development Pipeline at 2020 Research & Development Day

- *Primary Endpoint of Symptom Control Achieved in Phase 2 Dry Eye Disease Formulation Clinical Trial*
- *Statistically Significant Combined Data Across Multiple Dry Eye Disease Clinical Trials Suggests Potential Early and Potent Activity in Signs and Symptoms*
- *In Head-to-Head Clinical Trial, Tolerability of Reproxalap Superior to that of Xiidra® in Dry Eye Disease Patients over One Hour After Instillation*
- *Leading Ocular Surface Disease Expert Dr. Paul Karpecki to Highlight Treatment Challenges in Allergic Conjunctivitis and Dry Eye Disease*
- *Live Webcast Scheduled to Begin at Noon ET Today*

LEXINGTON, Mass., Feb. 24, 2020 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today will host the 2020 Research & Development Day (R&D Day) with investors and financial analysts in New York City to present recent clinical development updates and market opportunities for its novel investigational new drug product candidates in dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy. The event will include presentations from members of the Aldeyra executive team and Paul Karpecki, O.D., FAAO. Dr. Karpecki is Clinical Director, Corneal Services and Advanced Ocular Surface Disease at Kentucky Eye Institute and a clinician for Gaddie Eye Centers.

Aldeyra will announce that the Phase 2 novel formulation clinical trial in dry eye disease achieved the primary endpoint of symptom control. The double-masked, randomized, vehicle-controlled, multi-center, parallel-group clinical trial assessed the efficacy and safety of a novel formulation of 0.25% reproxalap topical ophthalmic solution compared to vehicle in 206 patients with moderate to severe dry eye disease. Relative to the formulation of 0.25% reproxalap topical ophthalmic solution used in prior clinical trials, the concentration of a single excipient was increased in the novel formulation. The primary efficacy endpoint was change from baseline versus vehicle in patient-reported ocular dryness score over two to twelve weeks of treatment. Relative to patients treated with vehicle, patients treated with reproxalap demonstrated statistically significant reduction in ocular dryness ($p=0.03$). Based on the results across the clinical studies conducted in dry eye disease to date, Aldeyra plans to meet with the U.S. Food and Drug Administration (FDA) prior to initiating Part 2 of the RENEW Trial and expects to provide an update on future development plans in dry eye disease following FDA feedback.

In addition, Aldeyra will present novel combined data analyses from the Phase 2b clinical trial and Part 1 of the Phase 3 RENEW Trial in dry eye disease. The analyses included approximately 460 patients treated with reproxalap for up to four weeks, during which site visits, formulation, and dosing regimen were the same across the trials. Statistically significant improvement over vehicle was demonstrated in the combined data for ocular dryness ($p = 0.008$) and nasal region fluorescein staining ($p = 0.003$).

Topical ocular reproxalap has now been studied in over 1,100 patients with no observed safety concerns reported; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

Aldeyra will also present the results of a head-to-head tolerability clinical trial of the current formulation of investigational new drug reproxalap and the novel formulation of reproxalap versus Xiidra® (lifitegrast ophthalmic solution) over one hour after drop instillation. The tolerability of both formulations of reproxalap, as assessed by a variety of drop experience scores including ocular discomfort, blurry vision, and taste disturbance, was statistically superior to that of Xiidra®. In a crossover design with a three-day washout period between visits, nineteen patients were exposed at each visit to either Xiidra®, the current formulation of reproxalap, or the novel formulation of reproxalap. No statistical differences were noted in tolerability between the current formulation of reproxalap and the novel formulation of reproxalap. The trial compared only tolerability under the aforementioned conditions.

“Reproxalap has now met pre-specified and FDA-sanctioned symptom endpoints in the formulation trial and in Part 1 of the RENEW Trial,” said Todd Brady, M.D., Ph.D., President and CEO of Aldeyra. “The recent clinical results, in addition to the combined trial analyses and head-to-head tolerability data released today, highlight a compelling development program for what we continue to believe could be the next novel entrant in the dry eye disease market.”

Topical ocular reproxalap is also being investigated in patients with allergic conjunctivitis in the Phase 3 INVIGORATE Trial. The INVIGORATE Trial, which will enroll approximately 120 patients, is a randomized, double-masked, crossover vehicle-controlled Phase 3 clinical trial to assess the efficacy and safety of 0.25% reproxalap topical ophthalmic solution compared to vehicle using an allergen chamber. Consistent with the company’s prior allergic conjunctivitis trials, the primary endpoint will be subject-reported ocular itching score. Top-line results from the INVIGORATE Trial are expected in the second half of 2020. In 2019, Aldeyra announced achievement of the primary endpoint of the Phase 3 ALLEVIATE Trial in allergic conjunctivitis, as well as statistically significant reductions in ocular itching and redness in an allergen chamber clinical trial.

Aldeyra will present an updated market assessment of allergic conjunctivitis, which affects more than 1 billion people worldwide,[i] including more than 100 million in the U.S.[ii] The signs and symptoms of allergic conjunctivitis – ocular itching, redness, and tearing – are persistently disturbing, affecting quality of life and leading to loss of work that can create a substantial economic burden for patients and families.[iii] The prevalence of allergic conjunctivitis is growing due to longer allergy seasons and the geographic spread of allergen-producing plants.

During Aldeyra's R&D Day, Dr. Paul Karpecki, a leading and internationally recognized expert in ocular surface disease, will discuss the clinical overlap between allergic conjunctivitis and dry eye disease, two of the most common anterior ocular inflammatory diseases. Allergic conjunctivitis and dry eye disease collectively represent the majority of inflammatory ocular surface disease, which affects more than 40% of people in the U.S.[iv]

"Inflammation is the common component of all ocular surfaces diseases, and it can often be difficult for doctors to differentiate between dry eye disease and allergic conjunctivitis," Dr. Karpecki said. "Many patients do not respond to currently available dry eye disease or allergic conjunctivitis therapies, and corticosteroids have long-term risks and side effects. Thus, there is a significant unmet medical need for a novel therapeutic option such as reproxalap, which has the potential to treat inflammation in multiple ocular surface diseases."

Aldeyra will also highlight the challenging patient experience with proliferative vitreoretinopathy (PVR), a serious, sight-threatening retinal disease with no approved treatment. Aldeyra is currently testing ADX-2191, an anti-inflammatory and anti-proliferative agent, in the Phase 3 GUARD Trial, a two-part, multi-center, randomized, controlled, adaptive clinical trial evaluating the efficacy of intravitreal injections of ADX-2191 versus standard-of-care for the prevention of PVR. The GUARD Trial will compare recurrent retinal detachment rates over a 24-week period following surgical repair of retinal detachment due to PVR or open globe injury. Patient enrollment in the GUARD Trial began in December 2019.

The R&D Day presentations are scheduled to begin at Noon (ET) today, February 24, 2020, in New York, NY. A live audio webcast of the presentation and a slide deck will be available via the company's Investor Relations website at https://ir.aldeyra.com/. Following the live webcast, an archived version will be available on the website for 90 days.

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 potential first-in-class 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 strategy, future operations, future financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to the clinical development or commercial potential of reproxalap, the novel formulation of reproxalap and ADX-2191. 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," "on track," "scheduled," "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 clinical 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 September 30, 2019, 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 those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2019, expected to be filed with the SEC in the first quarter of 2020.

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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[i] White Book on Allergy (2013 Update)

[ii] Singh K, Axelrod S, Bielory L. The epidemiology of ocular and nasal allergy in the United States, 1988-1994.J Allergy ClinImmunol.2010;126(4):778-783.e6

[iii] Andrew D. Pitt, Andrew F. Smith, Lynda Lindsell, Li Wern Voon, Peter W. Rose & Anthony J. Bron (2004) Economic and quality-of-life impact of seasonal allergic conjunctivitis in Oxfordshire, Ophthalmic Epidemiology, 11:1, 17-33, DOI: 10.1076/opep.11.1.17.26437

[iv] Khan RS, Rizvi S, Syed BA, Bielory L. Curr Opin Allergy Clin Immunol. 2019 Oct;19(5):503-509. doi: 10.1097/ACI.0000000000000562