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): November 9, 2021

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 November 9, 2021, Aldeyra Therapeutics, Inc. issued a press release (the "Press Release") to announce the completion of enrollment in the Phase 3 TRANQUILITY Trial of reproxalap ophthalmic solution in patients with dry eye disease and the reiteration of the Company's New Drug Application submission guidance. The Press Release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated November 9, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 9, 2021

ALDEYRA THERAPEUTICS, INC.

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

Exhibit 99.1

Aldeyra Therapeutics Announces Completion of Enrollment in Phase 3 TRANQUILITY Trial in Patients with Dry Eye Disease and Reiterates New Drug Application (NDA) Submission Guidance

- ***Top-Line Results from TRANQUILITY Expected This Quarter***
- ***Together with Recently Completed Phase 2 Clinical Trial, Positive Ocular Redness Results from TRANQUILITY Could Satisfy NDA Submission Requirements as Pivotal Trials for Improvement in an Objective Sign of Dry Eye Disease***
- ***Completed Phase 3 RENEW-Part 1 and Formulation Phase 2 Clinical Trials to be Submitted as Pivotal Trials in Satisfaction of NDA Symptom Requirements***
- ***Anticipated NDA Submission Expected in Early 2022***

LEXINGTON, Mass.--(BUSINESS WIRE)--November 9, 2021--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra or the Company), a biotechnology company developing novel immune-modulating therapies to treat ocular and systemic diseases, today announced completion of enrollment in the Phase 3 TRANQUILITY Trial of 0.25% reproxalap ophthalmic solution (reproxalap) for the treatment of patients with dry eye disease.

“Following the recent announcement of top-line results from our Phase 2 clinical trial, which achieved the primary endpoint of ocular redness and which we intend to submit as a pivotal trial, completion of enrollment in TRANQUILITY is a significant milestone as we advance reproxalap toward an anticipated NDA submission early next year for the treatment of dry eye disease,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “If the primary endpoint of ocular redness in TRANQUILITY is achieved, and in conjunction with two previously announced clinical trials demonstrating improvement in ocular dryness symptoms, we believe that the efficacy requirements for NDA submission will have been met.”

The multi-center, double-masked, parallel-group TRANQUILITY Trial enrolled 300 patients randomized equally to receive either reproxalap or vehicle. Patients received four doses one day prior to, and two doses on the day of exposure to, a 90-minute dry eye chamber with minimal humidity, high airflow, and forced visual tasking. The primary endpoint of the TRANQUILITY Trial is ocular redness. Top-line results from the trial are expected this quarter.

Based on the results of the recently completed Phase 2 clinical trial, which enrolled 158 patients and achieved statistical significance in the primary endpoint of ocular redness, TRANQUILITY is at least 90% powered to detect a statistically significant difference in ocular redness. TRANQUILITY is one of two identically designed Phase 3 clinical trials Aldeyra is conducting in patients with dry eye disease. Enrollment in the second trial, TRANQUILITY-2, is ongoing. If successful, either TRANQUILITY or TRANQUILITY-2 could complete NDA submission requirements for demonstration of improvement in an objective sign of dry eye disease.

Per draft U.S. Food and Drug Administration (FDA) guidance, to be considered for regulatory approval in the United States, a product candidate for the treatment of dry eye disease must demonstrate efficacy in an objective sign in at least two clinical trials and efficacy in a subjective symptom in at least two clinical trials. For satisfaction of symptom efficacy requirements, Aldeyra intends to submit two previously completed adequate and well-controlled symptom trials that pre-specified patient-reported ocular dryness score as a primary endpoint, the RENEW-Part 1 Trial and the Formulation Phase 2 clinical trial. For satisfaction of the sign efficacy requirements, Aldeyra intends to submit the recently completed Phase 2 clinical trial and, if positive, either TRANQUILITY or TRANQUILITY-2, all of which pre-specify ocular redness as a primary endpoint.

“With its safety and efficacy profile—demonstrated in clinical trials encompassing more than 1,300 patients in aggregate—reproxalap has the potential to provide relief to the estimated 34 million adults in the U.S. who suffer from persistently disturbing symptoms and ocular redness caused by dry eye disease,” Dr. Brady stated.

More information on TRANQUILITY can be found on www.clinicaltrials.gov, (NCT04674358).

About Reproxalap

Reproxalap, an investigational new drug, is a novel small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap is currently in Phase 3 clinical development as a 0.25% ophthalmic solution for the treatment of dry eye disease and allergic conjunctivitis, two ocular inflammatory diseases that often occur together.

About Aldeyra Therapeutics, Inc.

Aldeyra Therapeutics, Inc. is a biotechnology company developing novel immune-modulating therapies to treat ocular and systemic diseases. Two of the Company's lead product candidates, reproxalap and ADX-629, target RASP, which are pre-cytokine, systems-based mediators of inflammation. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The Company's clinical pipeline also includes ADX-2191 (methotrexate for intravitreal injection), a drug candidate in Phase 3 testing for the prevention of proliferative vitreoretinopathy. For more information, visit https://www.aldeyra.com/ and follow us on LinkedIn, Facebook, and Twitter.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Aldeyra's development plans and expectations for its product candidates, including plans and expectations relating to current or future clinical development and regulatory progress of reproxalap in dry eye disease. 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. In addition, FDA draft guidance and discussions with the Company are not binding on the agency. 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, including the timing of the 12-month safety trial of reproxalap in dry eye disease; 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 in clinical trials focused on the same or on different indications; the risk that the FDA may not accept Aldeyra's NDA submission for review; the risk that the results from smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale trials or the remainder of a clinical trial; 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; political, economic, legal, social and health risks, including the COVID-19 pandemic and related public health measures, that may affect Aldeyra's business or the global economy; 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, 2020 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://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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