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): May 24, 2022

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 May 24, 2022, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") to announce the designation of Schirmer test as the sole primary endpoint in the Phase 3 TRANQUILITY-2 Trial of reproxalap in dry eye disease. 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 May 24, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Dated May 24, 2022

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady

Name: Todd C. Brady M.D., Ph.D.
Title: Chief Executive Officer

Exhibit 99.1

Aldeyra Therapeutics Designates Schirmer Test as Sole Primary Endpoint in Phase 3 TRANQUILITY-2 Trial of Reproxalap in Dry Eye Disease

Selection Follows Post-Hoc Analysis Demonstrating Statistical Significance of Reproxalap Over Vehicle in Ocular Redness in Completed TRANQUILITY Trial

LEXINGTON, Mass.--(BUSINESS WIRE)--May 24, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced the designation of Schirmer test, a measure of tear production, as the sole primary endpoint in the Phase 3 TRANQUILITY-2 clinical trial of reproxalap in patients with dry eye disease.

The selection of Schirmer test as the primary endpoint for TRANQUILITY-2 followed Aldeyra's announcement last week of favorable results of post-hoc analyses from the completed Phase 3 TRANQUILITY and Phase 2 clinical trials of reproxalap in patients with dry eye disease. Using computer automated grading of digital photography, the analyses indicated that reproxalap demonstrated a statistically significant reduction in ocular redness.

"The opportunity to submit a New Drug Application for dry eye disease based on the achievement of two objective signs is significant," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Based on our discussions with ophthalmologists, optometrists, and other key opinion leaders about the unmet medical needs in dry eye disease, ocular redness is a substantial concern for many patients, while Schirmer test has long been considered by many eyecare providers as the benchmark sign endpoint for regulatory approval."

Christopher E. Starr, M.D., F.A.C.S., Attending Ophthalmologist at New York-Presbyterian Hospital and Associate Professor of Ophthalmology at Weill Cornell Medicine, said, "From a sign approvability standpoint, there is tremendous benefit in having a dry eye disease drug candidate that is capable of reducing ocular redness and enhancing tear production. In that regard, reproxalap has the potential to be highly differentiated from and a welcome addition to current standard-of-care therapies."

Pending the results from TRANQUILITY-2 and discussion with the U.S. Food and Drug Administration (FDA), Aldeyra intends to submit the Schirmer test results of both TRANQUILITY trials in support of its New Drug Application (NDA) submission. In the TRANQUILITY and TRANQUILITY-2 trials, Schirmer test was assessed after four doses of reproxalap or vehicle over a single day. A secondary endpoint in TRANQUILITY, Schirmer test scores were statistically higher in reproxalap-treated patients ($p=0.0001$), and the post-hoc proportion of Schirmer test responders of 10mm or greater was statistically higher ($p<0.0001$) in reproxalap-treated patients, relative to vehicle. The acute increase in Schirmer test scores following administration of reproxalap observed in TRANQUILITY is consistent with symptomatic activity observed as soon as one week after dosing in the Phase 3 RENEW trial.

“There is a great unmet need for faster-acting non-steroidal agents as part of our clinical armamentarium,” said Kelly K. Nichols, O.D., M.P.H., Ph.D., F.A.A.O., Dean, School of Optometry, The University of Alabama at Birmingham. “I am enthusiastic about the results reproxalap has demonstrated to date.”

Top-line results from TRANQUILITY-2 are expected in the second quarter of 2022. Pending discussion with the FDA and enrollment of the ongoing 12-month safety trial of reproxalap in dry eye disease, NDA submission for dry eye disease is expected to occur mid-2022.

About Aldeyra

Aldeyra develops innovative therapies designed to treat immune-mediated diseases. Our approach is to discover pharmaceuticals that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 clinical testing for the treatment of systemic immune-mediated diseases. Our pipeline also includes ADX-2191 (intravitreal methotrexate 0.8%), in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. 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 submission of a potential New Drug Application; the anticipated timing of results from Aldeyra's clinical trials; expectations regarding the FDA's acceptance of Aldeyra's post-hoc review of data and agreement with Aldeyra's methods of analyzing data; and Aldeyra's projected cash runway. 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 or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, 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 results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent 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) and obtain reimbursement for 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 subsequent public health measures, and war or other military actions, 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, 2021, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, 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.

Contacts

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