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 14, 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 September 14, 2022, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") to announce that it has received the official minutes from the Company's pre-New Drug Application meeting with the U.S. Food and Drug Administration and provide a corporate update. 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 September 14, 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 September 14, 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 Announces Positive Dry Eye Disease Pre-NDA Meeting with the FDA and Highlights Upcoming Corporate Milestones

Dry Eye Disease NDA for Reproxalap Expected to be Submitted in the Fourth Quarter of 2022

Pre-NDA Meeting for ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma Scheduled for the Fourth Quarter of 2022

Results from Part 1 of the Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected in the Third or Fourth Quarter of 2022

Results from the Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa Expected in the First Half of 2023

Results from the Phase 3 INVIGORATE-2 Trial of Reproxalap in Allergic Conjunctivitis Expected in 2023

LEXINGTON, Mass.--(BUSINESS WIRE)--September 14, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that, following the recent receipt of official minutes from its pre-NDA (New Drug Application) meeting with the U.S. Food and Drug Administration (FDA), the Company remains on schedule to submit an NDA in the fourth quarter of 2022 requesting marketing approval of the novel RASP modulator reproxalap, an investigational new drug, for the treatment of dry eye disease.

“Based on the outcome of our pre-NDA meeting, we believe that we have aligned with the FDA on the content of the regulatory package that will support what we expect to be a uniquely comprehensive NDA submission for the treatment of dry eye disease, encompassing data demonstrating improvement that may occur within minutes of drug administration in symptoms and three different objective signs,” stated Todd C. Brady, M.D., Ph.D., Aldeyra’s President and Chief Executive Officer. “In contrast to currently available dry eye therapies that may require weeks of administration to achieve even modest benefit, the rapid onset of activity of reproxalap observed in clinical trials represents a potential paradigm shift in the treatment of dry eye disease.”

Consistent with prior guidance, with results from five adequate and well-controlled completed clinical trials, Aldeyra intends to submit the NDA with data for ocular dryness symptom score, ocular redness, Schirmer test, and Schirmer test ≥10 mm responder analysis. The NDA efficacy package is expected to include activity ranging from within minutes of drug administration to up to 12 weeks of treatment, crossover and parallel-group clinical trial designs, and assessment in dry eye chamber challenge and natural environment settings. In addition to efficacy data, Aldeyra plans to submit up to 12 months of safety data. Topical ocular reproxalap has been studied in more than 2,000 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

In addition to the planned NDA submission for reproxalap in dry eye disease, Aldeyra highlighted the following expected upcoming corporate milestones:

- The pre-NDA meeting for ADX-2191 for the treatment of primary vitreoretinal lymphoma has been scheduled for the fourth quarter of 2022.
- Results from Part 1 of the Phase 3 GUARD trial of ADX-2191 in proliferative vitreoretinopathy are expected in the third or fourth quarter of 2022.
- Results from the Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa are expected in the first half of 2023.
- Results from the Phase 3 INVIGORATE-2 trial of reproxalap in allergic conjunctivitis are expected in 2023.

About Reproxalap

Reproxalap, an investigational new drug candidate, is a first-in-class small-molecule modulator of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease. Reproxalap's mechanism of action has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect 39 million or more adults in the United States.[1] The disease is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, diminished quality of life, and in severe cases, permanent vision impairment. Among many physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate and often requires weeks or months to demonstrate activity. In patients with dry eye disease, RASP may contribute to ocular inflammation, diminished tear production, ocular redness, and changes in tear lipid composition.[2] By diminishing RASP levels, Aldeyra's lead RASP modulator reproxalap represents a novel and differentiated approach for the treatment of the symptoms and signs of dry eye disease.

About Aldeyra

Aldeyra is a clinical-stage biotechnology company developing 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 late-stage 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 Aldeyra's future expectations, plans and prospects, including without limitation statements regarding: plans for an NDA filing for reproxalap for the treatment of dry eye disease, and the potential timing of such submission; Aldeyra’s belief in the adequacy of the data it plans to submit in the NDA; the potential for FDA acceptance of an NDA for reproxalap; the potential for regulatory approval and commencement of commercialization of reproxalap and Aldeyra’s goals as to timing; the potential profile and benefit of reproxalap in dry eye disease; anticipated clinical or regulatory milestones for ADX-2191, including expectations regarding the results of scheduled pre-NDA meetings and clinical trials; and other statements regarding the goals, opportunity and potential for reproxalap and ADX-2191, and for Aldeyra’s business. 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,” “on schedule,” “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, enrollment 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 June 30, 2022, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. Additional factors may be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, expected to be filed with the SEC in the fourth quarter of 2022.

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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[1] Company estimates and Paulsen AJ, Cruickshanks KJ, Fischer ME, et al. Dry eye in the beaver dam offspring study: prevalence, risk factors, and health-related quality of life. Am J Ophthalmol. 2014;157(4):799-806.
[2] Choi W, Lian C, Ying L, Kim GE, You IC, Park SH, Yoon KC. Expression of Lipid Peroxidation Markers in the Tear Film and Ocular Surface of Patients with Non-Sjogren Syndrome: Potential Biomarkers for Dry Eye Disease. Curr Eye Res. 2016 Sep;41(9):1143-9. doi: 10.3109/02713683.2015.1098707. Epub 2016 Jan 5. PMID: 26731289.

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