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): March 17, 2026

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 7.01. Regulation FD Disclosure.

On March 17, 2026, Aldeyra Therapeutics, Inc. ("Aldeyra" or the "Company") issued a press release (the "Press Release") to announce receipt of a Complete Response Letter ("2026 Complete Response Letter") from the U.S. Food & Drug Administration ("FDA") regarding the Company's New Drug Application for reproxalap ("reproxalap NDA"), an investigational drug candidate, for the treatment of dry eye disease. The Press Release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

As reported under Item 7.01 of this Current Report on Form 8-K, on March 17, 2026, Aldeyra announced receipt of the 2026 Complete Response Letter. The 2026 Complete Response Letter stated that there is "a lack of substantial evidence consisting of adequate and well-controlled investigations … that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling" and that "the application has failed to demonstrate efficacy in adequate and well controlled studies in the treatment of signs and symptoms of dry eye disease." The 2026 Complete Response Letter also stated that the "inconsistency of study results raises serious concerns about the reliability and meaningfulness of the positive findings" and that "the totality of evidence from the completed clinical trials does not support the effectiveness of the product." Consistent with prior NDA reviews of reproxalap, no safety or manufacturing concerns were identified. During the NDA review, label drafts were provided by the FDA in December 2025 and again in March 2026. Aldeyra does not believe that label negotiations were completed. The FDA recommended that the reasons for failure in certain trials be explored, and that populations or certain conditions in which reproxalap may be effective be identified. The FDA did not recommend conducting additional trials or request submission of additional confirmatory evidence. In addition, Aldeyra announced that cash, cash equivalents, and marketable securities as of December 31, 2025 are expected to support operations into 2028.

The following risk factor is provided to supplement Aldeyra's risk factors previously disclosed under the heading "Risk Factors" in Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2025.

Aldeyra's success in obtaining regulatory approval of reproxalap from the FDA depends on Aldeyra's ability to address the issues raised by the FDA in the 2026 Complete Response Letter, and address any issues the FDA may raise in the future.

Aldeyra resubmitted an NDA (the "reproxalap NDA") for reproxalap for the treatment of the signs and symptoms of dry eye disease in October 2024. In November 2024, the FDA accepted the reproxalap NDA for filing and set a Prescription Drug User Fee Act date of April 2, 2025. On April 3, 2025, Aldeyra announced that it had received a Complete Response Letter from the FDA (the "2025 Complete Response Letter"). In the 2025 Complete Response Letter, the FDA stated that the reproxalap NDA "failed to demonstrate efficacy in adequate and well controlled studies in treating ocular symptoms associated with dry eyes" and that "at least one additional adequate and well controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye" should be conducted. The letter identified concerns with the data from the trial submitted to the reproxalap NDA that may have affected interpretation of the results, which the FDA stated may be related to methodological issues, including a difference in baseline scores across treatment arms. On May 5, 2025, Aldeyra announced the results from two additional dry eye disease trials, an additional dry eye chamber trial and a field trial. The additional dry eye chamber trial achieved the primary endpoint (P=0.002) of reducing patient-reported ocular discomfort in a dry eye chamber. In June 2025, Aldeyra resubmitted the reproxalap NDA, which, based on written agreement with the FDA, primarily consisted of results from the additional dry eye chamber trial. On July 17, 2025, Aldeyra announced that the FDA accepted the reproxalap NDA for review and assigned a PDUFA date of December 16, 2025. On December 15, 2025, Aldeyra announced that the FDA had requested submission of the clinical study report for the field trial,

triggering an extension of the PDUFA date to March 16, 2026. On March 17, 2026, Aldeyra announced that it had received a Complete Response Letter from the FDA (the "2026 Complete Response Letter"). The 2026 Complete Response Letter stated that there is "a lack of substantial evidence consisting of adequate and well-controlled investigations … that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling" and that "the application has failed to demonstrate efficacy in adequate and well controlled studies in the treatment of signs and symptoms of dry eye disease." The 2026 Complete Response Letter also stated that the "inconsistency of study results raises serious concerns about the reliability and meaningfulness of the positive findings" and that the "totality of evidence from the completed clinical trials does not support the effectiveness of the product." Aldeyra intends to request a Type A meeting with the FDA to understand the actions needed for approval of the reproxalap NDA.

In connection with the review of a potential NDA resubmission or potential approval of the reproxalap NDA, the FDA could require additional studies or clinical trials, and the submission of the results of those studies or clinical trials before a potential NDA resubmission will be reconsidered, which would require Aldeyra to expend more resources than Aldeyra planned or that are available to Aldeyra, and could substantially delay acceptance and/or approval, if any, of a potential NDA resubmission. Any such requirement would increase Aldeyra's costs and delay approval and commercialization of reproxalap for the treatment of dry eye disease and would have a material adverse effect on Aldeyra's business and financial condition. There can be no assurance that the FDA will ever ultimately grant approval for reproxalap or that Aldeyra will continue to pursue approval for reproxalap, whether for financial reasons or for other reasons at the discretion of Aldeyra.

Even if reproxalap is approved for the treatment of dry eye disease, the FDA may restrict patient populations or conditions of use. Any regulatory approval of reproxalap, once obtained, may be withdrawn. Ultimately, the failure to obtain and maintain regulatory approvals would prevent reproxalap from being marketed and would have a material adverse effect on Aldeyra's business.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the outcome and expected timing of discussions with the FDA; the FDA's potential approval of reproxalap; the FDA's potential acceptance and/or approval of a potential NDA resubmission for reproxalap; a potential NDA resubmission or the supplemental responses to the FDA; Aldeyra's projected cash runway; and the Company's ability to successfully commercialize (alone or with others) reproxalap. Any statements about the Company's expectations, beliefs, plans, predictions, forecasts, objectives, assumptions, or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "believes," "can," "could," "may," "predicts," "potential," "should," "will," "estimate," "plans," "projects," "continuing," "ongoing," "expects," "intends," and similar words or phrases. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, these statements are not guarantees of future performance and involve risks and uncertainties which are subject to change based on various important factors, some of which are beyond the Company's control. The Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Current Report on Form 8-K and are subject to a number of risks, uncertainties and assumptions including, without limitation, risks and factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2025, which is on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, expected to be filed with the SEC in the second quarter of 2026. The Company does not undertake any obligation to update any forward-looking statements made in this Current Report on Form 8-K as a result of new information, future events or otherwise

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated March 17, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

ALDEYRA THERAPEUTICS, INC.

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

Dated March 17, 2026

Exhibit 99.1

Aldeyra Therapeutics Receives Complete Response Letter from the U.S. Food and Drug Administration for the Reproxalap New Drug Application for the Treatment of Signs and Symptoms of Dry Eye Disease

Lexington, Mass., March 17, 2026 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) of reproxalap, an investigational drug candidate, for the treatment of dry eye disease. The CRL stated that there is "a lack of substantial evidence consisting of adequate and well-controlled investigations … that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling" and that "the application has failed to demonstrate efficacy in adequate and well controlled studies in the treatment of signs and symptoms of dry eye disease." The letter also stated that the "inconsistency of study results raises serious concerns about the reliability and meaningfulness of the positive findings" and that the "totality of evidence from the completed clinical trials does not support the effectiveness of the product." Consistent with prior NDA reviews of reproxalap, no safety or manufacturing concerns were identified.

During the NDA review, label drafts were provided by the FDA in December 2025 and again in March 2026. Aldeyra does not believe that label negotiations were completed.

The FDA recommended that the reasons for failure in certain trials be explored, and that populations or certain conditions in which reproxalap may be effective be identified. The FDA did not recommend conducting additional trials or request submission of additional confirmatory evidence. As such, Aldeyra does not currently expect to pursue additional clinical trials, and intends to expeditiously request a Type A meeting to understand the actions needed for NDA approval. Per Prescription Drug User Fee Act (PDUFA) goals, the target Type A meeting date is within 30 days of receipt of the meeting request.

"To the thousands of American and Canadian patients who participated in our clinical trials and to the tens of millions of patients with dry eye disease worldwide, I want to assure you that we will work with urgency to support the FDA in enabling market access to what is, to our knowledge, the only drug with clinical activity within minutes of administration in patients with dry eye disease, a condition that is today treated with medications that require weeks or months of treatment to achieve even modest improvement," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

As of December 31, 2025, Aldeyra reported cash, cash equivalents, and marketable securities of $70 million, which are expected to support operations into 2028.

About Aldeyra
Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. Our approach is to develop pharmaceuticals that modulate protein systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Our product candidates include RASP (reactive aldehyde species) modulators ADX-248, ADX-246, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our late-stage product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma and retinitis pigmentosa.

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: the goals, opportunity, and potential for reproxalap; the outcome and expected timing of discussions with the FDA; and 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," "contemplates," "likely," "potential," "continue," "ongoing," "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, funding, 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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates, including as a result of the FDA not accepting Aldeyra's regulatory filings, issuing a complete response letter, or requiring additional clinical trials or data prior to review or approval of such filings or in connection with resubmissions of such filings; 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 different indications; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data; 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 future revenue, the timing of future 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 commercialization, marketing and manufacturing capabilities and strategy; 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; political, economic, legal, social, and health risks, public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; 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, 2025, which is 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 described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, expected to be filed with the SEC in the second quarter of 2026, and Aldeyra's other filings with the SEC.

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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