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): October 16, 2023 (October 10, 2023)

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 October 16, 2023, Aldeyra Therapeutics, Inc. ("Aldeyra" or the "Company") announced that it received minutes from a late-cycle review meeting (the "Minutes") with the U.S. Food and Drug Administration (the "FDA") relating to the new drug application ("NDA") for reproxalap for the treatment of the signs and symptoms of dry eye disease. The Minutes identified substantive review issues in connection with the NDA for reproxalap. The FDA stated that "[i]t does not appear that you have data to support the clinical relevance of the ocular signs to support your dry eye indication." In subsequent communications between Aldeyra and the FDA, Aldeyra has submitted responses to the FDA that Aldeyra believes to be sufficient to mitigate the identified issues, but the FDA has not directly opined on the sufficiency of the information submitted, has no legal obligation to review the information submitted by Aldeyra, and has indicated that Aldeyra needs to conduct an additional clinical trial to satisfy efficacy requirements. As such, based on the time remaining in the NDA review cycle, the FDA may not be in the position to approve the NDA for reproxalap on or about the Prescription Drug User Fee Act ("PDUFA") target action date of November 23, 2023 or afterwards, and it may issue a Complete Response Letter and require that Aldeyra conduct additional clinical trials and submit the results of those clinical trials before the application will be reconsidered.

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, 2022 and Aldeyra's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023.

Risks Related to the Potential Development and Commercialization of Reproxalap and Aldeyra's Product Candidates

To generate revenue, Aldeyra will depend on FDA approval and successful commercialization of reproxalap. If Aldeyra is unable to successfully obtain FDA approval, or FDA approval is delayed or limited, Aldeyra's ability to generate revenue will be significantly delayed.

Aldeyra's ability to generate revenue will depend on the successful development, regulatory approval, and commercialization of reproxalap. Aldeyra submitted to the FDA an NDA for reproxalap for the treatment of the signs and symptoms of dry eye disease in December 2022. In February 2023, the FDA accepted the reproxalap NDA for filing and set a PDUFA target action date of November 23, 2023. However, the FDA's decision to accept the NDA for filing and set a PDUFA target action date does not indicate that it has made any decision regarding approval nor does it guarantee approval by such date, if at all. The FDA has substantial discretion in the approval process and may disagree with Aldeyra's interpretation of or the sufficiency of the data from Aldeyra's clinical trials. Clinical trial results frequently are susceptible to varying interpretations and regulatory authorities may disagree on what are appropriate methods for analyzing data, which may delay, limit or prevent regulatory approvals. For example, Aldeyra has received Minutes from a late-cycle review meeting with the FDA, which noted substantive review issues in connection with the NDA for reproxalap for the treatment of the signs and symptoms of dry eye disease. In addition, during the review

of the reproxalap NDA, the FDA has requested certain chemistry, manufacturing, and controls ("CMC") details. In subsequent communications between Aldeyra and the FDA, Aldeyra has submitted responses to the FDA that Aldeyra believes to be sufficient to mitigate the identified review issues and address the CMC requests, but the FDA has not directly opined on the sufficiency of the information submitted, has no legal obligation to review the information submitted by Aldeyra, and has indicated that Aldeyra needs to conduct an additional clinical trial to satisfy efficacy requirements. As such, based on the time remaining in the NDA review cycle, the FDA may not be in the position to approve the NDA for reproxalap on or about the PDUFA target action date of November 23, 2023 or afterwards, which could result in the Company receiving a Complete Response Letter or the FDA notifying the Company of an extension in the PDUFA target action date. The FDA could require that Aldeyra conduct additional CMC studies or clinical trials and submit the results of those studies or clinical trials before the application will be reconsidered, which would require Aldeyra to expend more resources than Aldeyra planned or that are available to Aldeyra, and could substantially delay approval, if any, of Aldeyra's NDA. There can be no assurance that the reproxalap NDA will be approved in a timely manner or at all. If marketing approval for reproxalap is delayed, limited or denied, Aldeyra's ability to market reproxalap, and Aldeyra's ability to generate product sales, would be adversely affected.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the likelihood and timing of the FDA's potential approval of the NDAs for reproxalap by the PDUFA target action date, or at any other time; the adequacy of the data included in the NDA submission or the supplemental responses to the FDA; and the Company's ability to successfully commercialize 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, 2022 and the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023, which are on file with the SEC and available on the SEC's website at www.sec.gov. 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. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, expected to be filed with the SEC in the fourth quarter of 2023.

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.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady

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

Dated: October 16, 2023