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 1, 2023 (October 31, 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 1.01 Entry into a Material Definitive Agreement

On October 31, 2023 (the "Effective Date"), Aldeyra Therapeutics, Inc. ("Aldeyra" or the "Company") entered into an exclusive option agreement (the "Option Agreement") with AbbVie Inc. ("AbbVie"), pursuant to which Aldeyra granted AbbVie an exclusive option (the "Option") to obtain (a) a co-exclusive license in the United States to facilitate a collaboration with Aldeyra to develop, manufacture and commercialize reproxalap in the United States, (b) an exclusive license to develop, manufacture and commercialize reproxalap outside the United States, (c) a right of first negotiation for compounds that are owned or otherwise controlled by Aldeyra in the field of ophthalmology relating to treating conditions of the ocular surface and (d) a right to review data for any other compounds that are owned or otherwise controlled by Aldeyra in the fields of ophthalmology and immunology before such data is shared with any other third party, in each case for clauses (a) to (d), on the terms and conditions set forth in the form of Co-Development, Co-Commercialization and License Agreement attached as an exhibit to the Option Agreement (the "Collaboration Agreement").

AbbVie may exercise the Option by delivering written notice to Aldeyra ("Option Exercise Notice") at any time during the period following the Effective Date until: (i) if Aldeyra receives approval from the U.S. Food and Drug Administration (the "FDA") of its new drug application ("NDA") for reproxalap in dry eye disease ("FDA Decision" and the date of such approval, if any, the "FDA Decision Date") before December 15, 2023, then the tenth (10th) business day after the FDA Decision Date, (ii) if the FDA Decision Date does not occur before December 15, 2023, AbbVie has not delivered an Option Exercise Notice prior thereto, and AbbVie pays Aldeyra a non-refundable payment (the "Option Extension Fee"), then the earlier of (a) the tenth (10th) business day after the FDA Decision Date and (b) the date that is eighteen (18) months after the Effective Date; and (iii) if the FDA Decision Date does not occur before December 15, 2023, AbbVie has not delivered an Option Exercise Notice and AbbVie does not pay the Option Extension Fee, then December 23, 2023 (collectively, the "Exercise Period").

Unless terminated earlier by AbbVie by delivery of written notice to Aldeyra or by Aldeyra for breach following certain uncured, material breaches by AbbVie, the Option Agreement will terminate upon the earliest of (A) expiration of the Exercise Period, if AbbVie does not deliver an Option Exercise Notice during the Exercise Period; (B) expiration of the ten (10) business day period following Aldeyra's delivery (if any) of non-final updated schedules to the Collaboration Agreement following AbbVie's delivery of an Option Exercise Notice (the "Selected Schedule Evaluation Period"), if AbbVie does not deliver a written notice to Aldeyra requiring the parties to execute the Collaboration Agreement (the "Agreement Execution Notice") during the Selected Schedule Evaluation Period; (C) withdrawal of the Option Exercise Notice or Agreement Execution Notice following Aldeyra's delivery (if any) of final updated schedules to the Collaboration Agreement; and (D) execution of the Collaboration Agreement.

AbbVie has agreed to pay Aldeyra a non-refundable payment of $1 million no later than thirty days after the Effective Date in consideration of the Option (the "Option Payment"). The Option Extension Fee is $5 million. Upon AbbVie's delivery of the Agreement Execution Notice and the parties entering into the Collaboration Agreement, AbbVie would pay Aldeyra a $100 million upfront cash payment, less the Option Payment and the Option Extension Fee, if any. In addition, Aldeyra would be eligible to receive up to approximately $300 million in regulatory, and commercial milestone payments, inclusive of a $100 million milestone payment payable if the FDA Decision is received prior to or after the execution of the Collaboration Agreement. In the United States, Aldeyra and AbbVie would share profits and losses from the commercialization of reproxalap according to a split of 60% for AbbVie and 40% for Aldeyra. Outside of the United States, Aldeyra would be eligible to receive tiered royalties on net sales of reproxalap.

Unless earlier terminated, the Collaboration Agreement will continue in effect until the later of (a) the expiration of the last royalty term for reproxalap outside the United States and (b) the date that reproxalap is no longer being developed or commercialized in the United States. The Collaboration Agreement is subject to customary termination provisions including termination by a party for the other party's uncured, material breach. In the event of certain terminations of the Collaboration Agreement, Aldeyra is entitled to certain reversion rights with respect to reproxalap.

The Collaboration Agreement contains customary representations, warranties, covenants, and terms governing the prosecution and enforcement of intellectual property.

The foregoing summary of the Option Agreement and the Collaboration Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of such agreements. Aldeyra expects to file a copy of the Option Agreement, including the form of Collaboration Agreement attached as an exhibit thereto, subject to any applicable confidential treatment, as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2023.

The following risk factors are provided to supplement Aldeyra's risk factor previously disclosed in Aldeyra's Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 16, 2023, and 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

If Aldeyra remains responsible for funding further development and commercialization of reproxalap, it may be unable to raise the additional capital required to further develop and commercialize reproxalap or enter into a collaboration agreement with another pharmaceutical company with equivalent or comparable terms, or at all.

If the Option is not exercised, Aldeyra will be responsible for funding further development and commercialization of reproxalap, and it may be unable to raise the additional capital required to further develop and commercialize reproxalap or enter into a collaboration agreement with another pharmaceutical company with equivalent or comparable terms, or at all. If Aldeyra is unable to raise capital when needed or on attractive terms, it could be forced to delay, reduce or eliminate its research and development programs and its reproxalap commercialization efforts.

If Aldeyra is required to continue the development and commercialization of reproxalap on its own, it may need to build its marketing, sales, distribution, managerial and other non-technical capabilities to commercialize reproxalap or make arrangements with third parties to perform these services. The establishment and development of Aldeyra's own sales force or the establishment of a contract sales force to market reproxalap would be expensive and time-consuming and could delay any commercial launch. Moreover, Aldeyra cannot be certain that it will be able to successfully develop this capability. Aldeyra would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Aldeyra would also face competition in its search for third parties to assist it with the sales and marketing efforts of reproxalap.

If the Option is exercised and the Collaboration Agreement is executed, then pursuant to the terms of the Collaboration Agreement, Aldeyra would work closely with AbbVie to execute a commercialization plan for reproxalap in the United States, and this commercialization plan may never achieve its desired outcomes.

Pursuant to the terms of the Collaboration Agreement, Aldeyra and AbbVie would work to execute a joint commercialization plan for reproxalap in the United States, and execute upon the commercialization plan with the intention to optimize the commercial potential of reproxalap. If this collaboration is not successful, then Aldeyra's business, financial condition, and results of operations could 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 NDA 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; the likelihood and timing of the exercise of the Option or extension of the Exercise Period; 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, 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. 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. 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.

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: November 1, 2023