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 18, 2024 (November 15, 2024)

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 November 15, 2024, Aldeyra Therapeutics, Inc. (the "Company") entered into the Extension Side Letter (the "Extension Letter") with AbbVie Inc. ("AbbVie"), which amended certain terms of the Exclusive Option Agreement (the "Option Agreement") between the Company and AbbVie, dated October 31, 2023. The Extension Letter makes certain changes to the Option Agreement, among other things, providing that the Company will conduct certain launch activities, which costs shall not exceed mid-single-digit millions of dollars without AbbVie's approval, and which costs will be considered allowable expenses pursuant to the License Agreement (as defined in the Option Agreement) upon the delivery of AbbVie's written notice of exercising the Option and entry into the License Agreement (as defined in the Option Agreement), such that 60% of the Company's allowable expenses will be reimbursed by AbbVie in the event of exercise. If AbbVie does not deliver a written notice of exercising the Option and the Company and AbbVie do not execute the License Agreement, the Company will remain solely responsible for such launch activities costs. AbbVie has also independently initiated pre-commercialization planning activities. In addition, the Exercise Period (as defined in the Option Agreement) was modified to ten (10) business days following FDA Approval (as defined in the Option Agreement), provided that AbbVie shall provide the Company notice in case AbbVie determines that it will not exercise the Option (as defined in the Option Agreement).

The foregoing summary of the Extension Letter does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Extension Letter. Aldeyra expects to file a copy of the Extension Letter, subject to any applicable confidential treatment, as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2024.

Item 8.01. Other Events.

On November 18, 2024, the Company issued a press release (the "Press Release") to announce the Extension Letter and that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's resubmitted New Drug Application (NDA) for reproxalap, a first-in-class investigational new drug candidate, for the treatment of the signs and symptoms of dry eye disease, and has assigned a Prescription Drug User Fee Act (PDUFA) date of April 2, 2025. The Press Release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements contained in this Current Report on Form 8-K are "forward-looking statements" under the securities laws, including, but not limited to, statements regarding relating to the likelihood and timing of the FDA's potential approval of the resubmitted NDA for reproxalap by the PDUFA date of April 2, 2025, or at any other time, the adequacy of the data included in the previously submitted NDA and the resubmitted NDA, the potential profile, benefit and market size of reproxalap in dry eye disease should the resubmitted NDA for reproxalap be approved by the FDA. 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.

Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, Aldeyra's plans to develop and commercialize product candidates, if they are approved; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the likelihood and timing of the exercise of the Option by AbbVie pursuant to the Option Agreement with AbbVie; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; 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; the rate and degree of market acceptance of any of Aldeyra's product candidates; the rate and degree of market acceptance of any of Aldeyra's product candidates, following regulatory approval, if any; 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; 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 scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; 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; 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, 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, 2023, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, 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 conveyed in this Current Report on Form 8-K is provided only as of the date hereof, and Aldeyra undertakes no obligation to update any forward-looking statements included herein on account of new information, future events, or otherwise, except as required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated November 18, 2024
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 November 18, 2024

ALDEYRA THERAPEUTICS, INC.

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

Aldeyra Therapeutics Announces FDA Acceptance for Review of Reproxalap New Drug Application for the Treatment of Dry Eye Disease, Expands AbbVie Option Agreement

PDUFA Date is April 2, 2025

Lexington, Mass., November 18, 2024 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmitted New Drug Application (NDA) for topical ocular reproxalap, a first-in-class investigational new drug candidate, for the treatment of the signs and symptoms of dry eye disease. The FDA assigned a Prescription Drug User Fee Act (PDUFA) date of April 2, 2025. In conjunction with the acceptance of the NDA for review, Aldeyra announced the expansion of its exclusive option agreement with AbbVie Inc. (AbbVie).

“Based on the FDA’s acceptance of the NDA resubmission of reproxalap for dry eye disease for review, we are pleased to announce an expansion of our option agreement with AbbVie, highlighting the commitment of both companies to accelerating the potential availability of a novel dry eye disease therapy to patients and physicians,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra.

On October 31, 2023, Aldeyra entered into an option agreement with AbbVie. Under the terms of the agreement, AbbVie has the option to obtain a co-exclusive license to develop, manufacture, and commercialize reproxalap in the United States. Upon exercise of the option, AbbVie would pay Aldeyra a $100 million upfront cash payment, less previously paid option fees of $6 million. In addition, Aldeyra would be eligible to receive up to $300 million in regulatory and commercial milestone payments, inclusive of a $100 million milestone payment payable if the FDA approval for reproxalap for dry eye disease is received. In the United States, Aldeyra would share profits and losses with AbbVie from the commercialization of reproxalap according to a split of 60% for AbbVie and 40% for Aldeyra.

Per the expansion of the option agreement, Aldeyra will initiate certain pre-commercial activities, 60% of which will be paid by AbbVie and 40% of which will be paid by Aldeyra if the option is exercised. AbbVie has also independently initiated certain pre-commercial planning activities. The parties have also agreed to amend the expiration of the option to 10 business days from the date of FDA approval, if any, of reproxalap for dry eye disease.

About Reproxalap

Reproxalap is an investigational new drug candidate in development for the treatment of dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology. Reproxalap is a first-in-class small-molecule modulator of RASP, which are elevated in ocular and systemic inflammatory diseases. The mechanism of action of reproxalap has been supported by the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Reproxalap has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

About Aldeyra

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated and metabolic diseases. Aldeyra's 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. Aldeyra's product candidates include RASP (reactive aldehyde species) modulators ADX-629, ADX-248, ADX-743, ADX-631, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated and metabolic diseases. Aldeyra's 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 retinitis pigmentosa. For additional information, please visit www.aldeyra.com.

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 timing of the FDA's review, or approval of the resubmitted NDA for reproxalap by the PDUFA date and the adequacy of the data included in the original NDA and the resubmitted NDA; the likelihood and timing of the exercise of the Option; and Aldeyra's expectations regarding the labeling for reproxalap, if approved. 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; 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, 2023, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, 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.

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