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 2, 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 March 2, 2023, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") to announce that the U.S. Food and Drug Administration (FDA) accepted for Priority Review the New Drug Application (NDA) for ADX 2191 (methotrexate injection, USP), an investigational drug candidate, for the treatment of primary vitreoretinal lymphoma. The FDA assigned a Prescription Drug User Fee Act (PDUFA) date of June 21, 2023. The FDA noted that no potential filing review issues have been identified. 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 NDA for ADX-2191 by the PDUFA date of June 21, 2023, or at any other time and the potential profile, benefit and market size of ADX-2191 in primary vitreoretinal lymphoma should the NDA for ADX-2191 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 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; the current and potential future impact of the COVID-19 pandemic on Aldeyra's business, results of operations and financial position; 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, 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; 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 September 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 described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2022, expected to be filed with the SEC in the first quarter of 2023.

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 March 2, 2023
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 March 2, 2023

ALDEYRA THERAPEUTICS, INC.

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

FDA Accepts for Priority Review ADX-2191 New Drug Application for the Treatment of Primary Vitreoretinal Lymphoma

PDUFA Date is June 21, 2023

Planned U.S. Launch of ADX-2191 in Second Half of 2023, Pending Approval by the FDA

ADX-2191 with Potential to be the First FDA-Approved Drug Available for Patients Suffering from Primary Vitreoretinal Lymphoma

LEXINGTON, Mass.--(BUSINESS WIRE)--March 2, 2023--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced that the U.S. Food and Drug Administration (FDA) accepted for Priority Review the New Drug Application (NDA) for ADX-2191 (methotrexate injection, USP), an investigational drug candidate, for the treatment of primary vitreoretinal lymphoma. The FDA assigned a Prescription Drug User Fee Act (PDUFA) date of June 21, 2023. The FDA noted that no potential filing review issues have been identified.

“The FDA’s decision to grant Priority Review with a PDUFA date four months from NDA acceptance underscores the significant need for an FDA-approved treatment of primary vitreoretinal lymphoma, a rare but potentially fatal cancer,” stated Todd C. Brady, M.D., Ph.D., Aldeyra’s President and Chief Executive Officer. “We are working closely with the FDA during the review process to bring ADX-2191 to patients as quickly as possible, and plan to launch ADX-2191 in the United States in the second half of this year, pending approval by the FDA.”

The NDA submission is supported by a combination of more than three decades of published literature on the safety and efficacy of methotrexate, the active ingredient of ADX-2191, for the treatment of primary vitreoretinal lymphoma, in addition to safety data from the recently completed Phase 3 GUARD Trial of ADX-2191 in patients with proliferative vitreoretinopathy. During the Phase 3 GUARD Trial, no safety signals were observed, and ADX-2191 was well tolerated; there were no observed treatment-emergent serious adverse events. The most common adverse event associated with ADX-2191 treatment was punctate keratitis, a frequently observed side effect of intravitreal methotrexate, that was most commonly mild in severity.

About ADX-2191

ADX-2191 (methotrexate injection, USP) is a sterile, non-compounded intravitreal formulation of methotrexate for the potential prevention or treatment of specific rare retinal diseases, including primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and retinitis pigmentosa. The ADX-2191 intravitreal formulation is preservative-free, is designed to be vitreous-compatible, and is optimized for excipient composition, viscosity, density, tonicity, pH, concentration, and volume of administration. ADX-2191 has received FDA Orphan Drug Designation for the prevention of proliferative vitreoretinopathy, and for the treatment of primary vitreoretinal lymphoma and retinitis pigmentosa.

About Primary Vitreoretinal Lymphoma

Primary vitreoretinal lymphoma is a rare, aggressive, and potentially fatal retinal cancer that is diagnosed in approximately 300 to 600 patients in the United States per year. The median survival for newly diagnosed patients is less than five years. No approved treatments are currently available, though intravitreal injection of compounded methotrexate represents the current standard of care.

About Aldeyra

Aldeyra Therapeutics is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover and develop 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. Our product candidates include RASP (reactive aldehyde species) modulators ADX-629, ADX-246, ADX-248, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our pre-commercial product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease (under U.S. Food and Drug Administration New Drug Application review) and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of primary vitreoretinal lymphoma (under U.S. Food and Drug Administration New Drug Application review), proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. 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 relating to the likelihood and timing of the FDA's potential approval of the NDA for ADX-2191 by the PDUFA date of June 21, 2023, or at any other time and the potential profile, the adequacy of the data included in the NDA submission for ADX-2191, the timing of the potential launch of ADX-2191, if approved, for treatment of primary vitreoretinal lymphoma, benefit and market size of ADX-2191 in primary vitreoretinal lymphoma should the NDA for ADX-2191 be approved by the FDA. 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 are subject to adjustment depending on recruitment rate, regulatory review, which regulatory review timeline may be flexible and subject to change based on the regulator's workload and other potential review issues, 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, 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 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; the current and potential future impact of the COVID-19 pandemic on Aldeyra's business, results of operations and financial position; 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, 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; 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 September 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/. 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Contacts

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