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): December 21, 2022

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 December 21, 2022, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing the submission of a New Drug Application to the U.S. Food and Drug Administration for ADX-2191, an investigational drug candidate, for the treatment of primary vitreoretinal lymphoma. The Press Release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated December 21, 2022
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 December 21, 2022

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady

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

Exhibit 99.1

Aldeyra Therapeutics Submits New Drug Application to the U.S. Food and Drug Administration for ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma

LEXINGTON, Mass.--(BUSINESS WIRE)--December 21, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ADX-2191 (methotrexate injection, USP), an investigational drug candidate, for the treatment of primary vitreoretinal lymphoma, a rare but potentially fatal cancer with no FDA-approved therapy.

The NDA submission is supported by a combination of published literature on the safety and efficacy of methotrexate for the treatment of primary vitreoretinal lymphoma and safety data from the recently completed Phase 3 GUARD Trial of ADX-2191 for the prevention of 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. In the Phase 3 GUARD Trial, the incidence of punctate keratitis with ADX-2191 administration was observed to be less than that previously reported with intravitreal injection of compounded methotrexate.[1]

“Compounding methotrexate for intravitreal injection, the current standard of care for primary vitreoretinal lymphoma, poses several challenges for physicians and patients, including risk of infection and increased injection volume, potentially leading to ocular hypertension and corneal inflammation,” stated Todd C. Brady, M.D., Ph.D., Aldeyra’s President and Chief Executive Officer. “ADX-2191 is a novel formulation of methotrexate that is designed to be vitreous-compatible and has the potential to be the first marketed drug for patients suffering from primary vitreoretinal lymphoma.”

ADX-2191 has received FDA Orphan Drug Designation for the treatment of primary vitreoretinal lymphoma. In addition, as part of the NDA submission, Aldeyra requested Priority Review Designation, which reduces the review period during which the FDA aims to take action on an NDA to within 6 months, compared to 10 months under standard review.

A Type C meeting with the FDA to discuss the completion of clinical development of ADX-2191 for the prevention of proliferative vitreoretinopathy is planned for the first half of 2023, and results from the Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa are expected in the first half of 2023.

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 4.83 years. The most common ocular complaints reported by patients include blurred vision, painless loss of vision, floaters, red eye, and photophobia. No approved treatments are currently available, though intravitreal injection of compounded methotrexate represents the current standard of care.[2]

About Aldeyra

Aldeyra Therapeutics is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover 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 pre-commercial product candidates are reproxalap, a potential treatment for dry eye disease and allergic conjunctivitis, and ADX-2191, a potential treatment for primary vitreoretinal lymphoma, proliferative vitreoretinopathy, and other rare sight-threatening retinal diseases. In addition, we are developing other product candidates, including ADX-629 and chemically related molecules, for the potential treatment of systemic and retinal immune-mediated 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 regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding Aldeyra's belief in the adequacy of the data it submitted in the NDA for ADX-2191; the potential for FDA acceptance of an NDA for ADX-2191; the potential for regulatory approval and commencement of commercialization of ADX-2191 and Aldeyra's goals as to timing; the potential profile and benefit of ADX-2191 in primary vitreoretinal lymphoma; the planned timing of the Type C meeting with the FDA to discuss the completion of clinical development of ADX-2191 for the prevention of proliferative vitreoretinopathy; and the expected timing of results from the Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa. 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 may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, 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; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, and endpoints acceptable to applicable regulatory authorities; 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; 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 risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial; 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 revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; 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; 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 limited sales and marketing infrastructure; 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; 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/.

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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[1] Annals of Hematology, 95(4), 593–601, 2016.
[2] Aldeyra internal estimates. Data on file; Primary Vitreoretinal Lymphoma by D. J. Wilson on AAO EyeWiki; M. Sagoo, Survey of Ophthalmology (2014); Grimm et. al., Annals of Oncology (2007).

Contacts

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