UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Plaintiff, v. ALDEYRA THERAPEUTICS, INC., TODD C. BRADY, JOSHUA REED, and BRUCE GREENBERG, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Aldeyra Therapeutics, Inc. ("Aldeyra" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Aldeyra securities between

March 17, 2022 and June 20, 2023, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Aldeyra, a biotechnology company, develops and commercializes medicines for immune-mediated diseases. The Company is currently developing ADX-2191, a dihydrofolate reductase inhibitor for the treatment of primary vitreoretinal lymphoma cancer, proliferative vitreoretinopathy, and retinitis pigmentosa, as well as rare retinal diseases characterized by inflammation and vision loss.

3. In December 2022, Aldeyra submitted a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") for ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma (the "ADX-2191 NDA").

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the ADX-2191 NDA did not include adequate and well-controlled investigations and thus failed to show substantial evidence of ADX-2191's effectiveness; (ii) as a result, the FDA was unlikely to approve the ADX-2191 NDA in its current form; (iii) accordingly, the Company had overstated ADX-2191's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On June 21, 2023, Aldeyra issued a press release "announc[ing] receipt of a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the 505(b)(2) New Drug Application (NDA) of ADX-2191 (methotrexate for injection, USP), an investigational

drug candidate, for the treatment of primary vitreoretinal lymphoma (PVRL)." The press release stated that "[a]lthough no safety or manufacturing issues with ADX-2191 were identified, the FDA stated that there was a 'lack of substantial evidence of effectiveness' due to 'a lack of adequate and well-controlled investigations' in the literature-based NDA submission."

6. On this news, Aldeyra's stock price fell $2.92 per share, or 27.44%, to close at $7.72 per share on June 21, 2023.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Aldeyra is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Aldeyra securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Aldeyra is a Delaware corporation with principal executive offices located at 131 Hartwell Avenue, Suite 320, Lexington, Massachusetts 02421. Aldeyra's common stock trades in an efficient market on the NASDAQ under the ticker symbol "ALDX".

14. Defendant Todd C. Brady ("Brady") has served as Aldeyra's Chief Executive Officer at all relevant times.

15. Defendant Joshua Reed ("Reed") served as Aldeyra's Chief Financial Officer ("CFO") from prior to the start of the Class Period until April 2022.

16. Defendant Bruce Greenberg ("Greenberg") has served as Aldeyra's Interim CFO since April 2022.

17. Defendants Brady, Reed, and Greenberg are sometimes referred to herein as the "Individual Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of Aldeyra's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Aldeyra's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Aldeyra, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then

materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

19. Aldeyra and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

20. Aldeyra, a biotechnology company, develops and commercializes medicines for immune-mediated diseases. The Company is currently developing ADX-2191, a dihydrofolate reductase inhibitor for the treatment of primary vitreoretinal lymphoma cancer, proliferative vitreoretinopathy, and retinitis pigmentosa, as well as rare retinal diseases characterized by inflammation and vision loss.

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on March 17, 2022, when Aldeyra issued a press release announcing the Company's 2021 financial results and recent corporate highlights. The press release quoted Defendant Brady, stating, in relevant part:

> "In addition to our planned completion of clinical development for reproxalap in dry eye disease, 2022 is expected to highlight data milestones for our systemic and retinal disease platforms," stated [Defendant Brady[.] "We are excited about the planned release this month of top-line data from our proof-of-concept clinical trials of ADX-629, a first-in-class RASP modulator, across a variety of systemic inflammatory diseases, and we look forward to reporting results of our recently initiated clinical trial of ADX-2191 in retinitis pigmentosa in the second half of this year."

22. That same day, Aldeyra filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2021 (the "2021 10-K"). In discussing the markets for the Company's product candidates, the 2021 10-K stated, in relevant part:

Proliferative Vitreoretinopathy, Primary Vitreoretinal Lymphoma, and Other Retinal Diseases

PVR is a rare inflammatory disorder of the retina that leads to severe retinal scarring and blindness, and is the leading cause of failure of retinal reattachment surgery. Over 50% of PVR cases result in severe uncorrectable vision loss (visual acuity of 20/320 or worse), and 76% of PVR patients suffer from at least moderate uncorrectable vision loss. PVR occurs after up to 10% of surgeries for retinal detachment and 50% or more of surgeries for open globe injury. Based on the prevalence of primary retinal detachment, in addition to retinal detachment that occurs as a result of trauma, we estimate that there are, in aggregate, approximately 20,000 treatable cases of PVR in the United States, Europe, and Japan. ***By inhibiting cell growth and thereby diminishing scar formation, ADX-2191 has the potential to be the first FDA-approved drug for prevention of PVR***. In April 2018, ADX-2191 received orphan drug designation from the FDA for the prevention of PVR and, in June 2020, ADX-2191 was designated an orphan medicinal product by the European Commission for the treatment of retinal detachment. In September 2019, ADX-2191 received fast track designation from the FDA for the prevention of PVR.

Primary vitreoretinal lymphoma (PVRL) is a rare, aggressive, high-grade cancer that arises in the vitreous and retina. An estimated 2,900 people in the United States suffer from PVRL, and approximately 600 new cases of PVRL are diagnosed in the United States per year. The median survival for newly diagnosed patients is less than five years. In January 2021, we received from the FDA preliminary written comments in preparation for a Pre-IND ("Investigational New Drug") Type B meeting regarding ADX-2191 for the treatment of PVRL. We believe the comments indicated that submission of a New Drug Application (NDA) for ADX-2191 for the treatment of PVRL may be possible without performing clinical trials. In the first quarter of 2021, we held a teleconference with the FDA to discuss the preliminary written comments and clarify the ADX-2191 NDA submission requirements for the treatment of PVRL. ***In July 2021, ADX-2191 received orphan drug designation from the FDA for the treatment of PVRL. ADX-2191 has the potential to be the first drug approved to treat PVRL.***[1]

22. Further, in describing the science supporting the Company's product candidates, the 2021 10-K stated, in relevant part:

The Potential of ADX- 2191 to Prevent Proliferative Vitreoretinopathy and Treat Primary Vitreoretinal Lymphoma

PVR is characterized by excessive replication and pro-inflammatory activity of retinal cells, at least a portion of which synthesize collagen, the principal

[1] All emphases included herein are added unless otherwise indicated.

> component of scar tissue. Retinal scarring can lead to impairment of vision, including blindness, as well as increased probability of further retinal detachments. Methotrexate, the active component of ADX-2191, is a dihydrofolate reductase inhibitor that has been used to treat cancer and autoimmune disease. The anti-proliferative and anti-inflammatory properties of dihydrofolate reductase inhibition are well described. In preclinical studies of primary cell cultures from PVR patients, dihydrofolate reductase inhibition reduced pathological cell proliferation and scar-like collagen deposition. Thus, the observed clinical activity of ADX-2191 in PVR is believed to be the result of down-regulation of aberrant retinal cell proliferation and activity, thereby leading to reduced retinal scarring. Initially as an intravenous medication and subsequently as an intraocular injection, methotrexate has also been used for decades as an anti-proliferative medication to treat PVRL. The goal of methotrextate therapy in PVRL is to prevent metastasis to the central nervous system.

24. Appended to the 2021 10-K as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Brady and Reed, attesting that "[t]he information contained in the [2021 10-K] fairly presents, in all material respects, the financial condition and results of operations of [Aldeyra]."

25. Also on March 17, 2022, Aldeyra hosted an earnings call with investors and analysts to discuss the Company's Q4 2021 results (the "Q4 2021 Earnings Call"). During the scripted portion of the Q4 2021 Earnings Call, Defendant Brady stated, in relevant part:

> 2022 promises to be an exciting year for Aldeyra as we enter a catalyst rich period that will highlight not only what we hope will be the successful completion of clinical development for reproxalap in dry eye disease, but also the emergence of our RASP modulator platform for the treatment of systemic autoimmune and inflammatory diseases and late-stage regulatory milestones for ADX-2191 for the treatment of certain rare retinal diseases. We believe that our systemic and retinal platforms are broadly underappreciated and underexposed, and we therefore attend to aggressively build awareness of these platforms throughout 2022 and beyond.
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> In January, we announced the completion of enrollment in Part 1 of the Phase 3 GUARD trial of ADX-2191 in patients with proliferative vitreoretinopathy or PVR, another rare retinal disease that can lead to loss of vision yet has no approved therapy. PVR is the leading cause of primary retinal detachment after surgical failure occurring in an estimated 5% to 10% of retinal detachments. Results from Part 1 of GUARD are expected in the second half of this year.

> To our knowledge, ADX-2191 is the first methotrexate formulation specifically designed to be compatible with vitreous, the fluid in the back of the eye. Thus, ADX-2191 represents a unique commercial opportunity. For example, off-label methotrexate injections are standard of care for the treatment of ocular lymphoma. Together with retinitis pigmentosa and PVR, the current indications for our ADX-2191 platform span three rare retinal diseases. In each indication, ADX-2191 has received the U.S. FDA's orphan drug designation.

26. On May 5, 2022, Aldeyra issued a press release announcing the Company's Q1 2022 financial results and recent corporate highlights. The press release quoted Defendant Brady, stating, in relevant part:

> "Consistent with our planned completion this quarter of clinical development for reproxalap in dry eye disease and the recently announced demonstration of clinical activity of ADX-629 in three inflammatory diseases, we are delivering on our strategy to expand our RASP platform from the front of the eye to systemic disease, including clinical trials in ethanol toxicity, chronic cough, minimal change disease, and Sjögren-Larsson Syndrome," stated [Defendant Brady[.] "Additionally, we continue to advance our intravitreal drug platform for the treatment of rare retinal diseases, highlighted by Phase 3 clinical trial results in proliferative vitreoretinopathy and Phase 2 clinical trial results in retinitis pigmentosa expected in the second half of this year."

27. That same day, Aldeyra hosted an earnings call with investors and analysts to discuss the Company's Q1 2022 results (the "Q1 2022 Earnings Call"). During the scripted portion of the Q1 2022 Earnings Call, Defendant Brady stated, in relevant part:

> We also continue to advance ADX-2191, our vitreous compatible formulation of methotrexate for orphan retinal diseases. An investigator-sponsored Phase II clinical trial in retinitis pigmentosa, conducted at Duke University Medical Center, has been initiated. In addition, in the first quarter, we completed enrollment in Part 1 of the Phase III GUARD trial in proliferative vitreoretinopathy. Results from both of these trials are expected in the second half of this year.

28. On August 5, 2022, Aldeyra issued a press release announcing the Company's Q2 2022 financial results and recent corporate highlights. The press release quoted Defendant Brady, stating, in relevant part, "[t]he second half of 2022 is highlighted by planned new drug applications in dry eye disease and primary vitreoretinal lymphoma, two diseases that are currently sub-

optimally treated." Further, the press release includes "Pre-NDA Meeting for ADX-2191 in Primary Vitreoretinal Lymphoma" as one of the Company's upcoming planned clinical and regulatory milestones, stating, in relevant part, "Aldeyra plans to conduct a pre-NDA meeting with the FDA in the second half of 2022 to discuss ADX-2191 for the treatment of primary vitreoretinal lymphoma. Pending discussion with the FDA, an NDA submission is planned for the second half of 2022."

29. That same day, Aldeyra hosted an earnings call with investors and analysts to discuss the Company's Q2 2022 results (the "Q2 2022 Earnings Call"). During the scripted portion of the Q2 2022 Earnings Call, Defendant Brady stated, in relevant part:

> The other accomplishment that stands out is the progress of ADX-2191, our investigational new drug platform for rare, but serious retinal diseases with no approved therapy.
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> The development program of ADX-2191 encompasses three such conditions. Number one, primary vitreoretinal lymphoma, which is a near universally fatal cancer; two, proliferative vitreoretinopathy or PVR a site-threatening condition that is the leading cause of failure of retinal reattachment surgery; and number three, retinitis pigmentosa, which is a rare group of genetic eye diseases.
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> The FDA has granted orphan drug designation to ADX-2191 for each of these indications and ADX-2191 is the first methotrexate formulation specifically designed to be compatible with a vitreous humor the fluid in the back of the eye, and therefore, represents what we believe to be a unique potential commercial opportunity for Aldeyra.

30. On November 10, 2022, Aldeyra issued a press release announcing the Company's Q3 2022 financial results and recent corporate highlights. The press release quoted Defendant Brady, stating, in relevant part, "[n]ow with two product candidates that could generate revenue as soon as next year, Aldeyra remains a leader in the development of systems-based therapeutic approaches for the treatment of diseases characterized by inflammation." Further, the press release included "Pre-NDA Meeting with the FDA for ADX-2191 in Primary Vitreoretinal Lymphoma"

as one of the Company's upcoming planned clinical and regulatory milestones, stating, in relevant part, "Aldeyra has scheduled a pre-NDA meeting with the FDA in the fourth quarter of 2022 to discuss ADX-2191 for the treatment of primary vitreoretinal lymphoma. Pending the results of the pre-NDA meeting, NDA submission may occur as soon as the end of 2022."

31. That same day, Aldeyra hosted an earnings call with investors and analysts to discuss the Company's Q3 2022 results (the "Q3 2022 Earnings Call"). During the scripted portion of the Q3 2022 Earnings Call, Defendant Brady stated, in relevant part:

> Today, I would like to share with you the progress we have made in advancing our lead pre-commercial product candidates, reproxalap, ADX-2191 toward regulatory approval. Individually, these products have the potential to provide us with unique revenue streams, while together, they represent an opportunity to build a formidable ocular franchise, encompassing both large and rare retinal diseases that are significantly underserved by currently available treatments.

32. On December 1, 2022, Aldeyra issued a press release entitled "Aldeyra Therapeutics Announces Positive Primary Vitreoretinal Lymphoma Pre-NDA Meeting with the FDA." The press release stated, in relevant part:

> Aldeyra [. . .] today announced that, following the recent receipt of official minutes from its pre-NDA (New Drug Application) meeting with the U.S. Food and Drug Administration (FDA), the Company plans to submit an NDA as soon as the end of 2022 for marketing approval of the investigational drug candidate ADX-2191 for the treatment of primary vitreoretinal lymphoma.
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> "Pending FDA review, ADX-2191 could be the first FDA-approved therapy for primary vitreoretinal lymphoma, a rare but potentially fatal cancer with a median survival of less than five years," stated [Defendant] Brady[.]
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> ADX-2191, which has received FDA Orphan Drug Designation for the treatment of primary vitreoretinal lymphoma, is a novel, vitreous-compatible formulation of methotrexate. The planned NDA submission is expected to include 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 in 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.
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> Based on the pre-NDA meeting minutes, Aldeyra intends to request Priority Review designation, which reduces the review period in which the FDA aims to take action on an NDA to within 6 months (compared to 10 months under standard review). The designation is intended to direct overall attention and resources to the evaluation of applications for drugs that, if approved, would represent significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

33. On December 21, 2022, Aldeyra issued a press release entitled "Aldeyra Therapeutics Submits New Drug Application to the U.S. Food and Drug Administration for ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma." The press release stated, in relevant part:

> 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.
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> 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.
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> "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 [Defendant] Brady[.] "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."

34. On March 2, 2023, Aldeyra issued a press release entitled "FDA Accepts for Priority Review ADX-2191 New Drug Application for the Treatment of Primary Vitreoretinal Lymphoma." The press release stated, in relevant part:

> 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.
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> "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 [Defendant] Brady[.] "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."
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> 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.

35. On March 9, 2023, Aldeyra issued a press release announcing the Company's full year 2022 financial results and recent corporate highlights. The press release stated, in relevant part:

> "Now with Priority Review Designation for the treatment of primary vitreoretinal lymphoma, ADX-2191 joins reproxalap as the second investigational drug candidate at Aldeyra under NDA review at the U.S. Food and Drug Administration," stated [Defendant] Brady[.] "In addition to potential approvals and supplemental NDA submissions, 2023 promises to be a catalyst-rich year for Aldeyra, as we continue to advance an industry-leading pipeline of novel RASP modulators for the treatment of systemic and retinal immune-mediated diseases."

Recent Corporate Highlights

- **Priority Review Designation Granted for NDA of ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma**: The New Drug Application (NDA) submission of ADX-2191 (methotrexate injection, USP), an investigational drug candidate, is supported by a combination of published literature on the safety and efficacy of intravitreal 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. The U.S. Food and Drug Administration (FDA) assigned a Prescription Drug User Fee Act (PDUFA) date of June 21, 2023. The FDA noted that no potential filing review issues had been identified.

36. That same day, Aldeyra filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2022 (the "2022 10-K"). The 2022 10-K contained substantively similar descriptions of the markets for and science supporting the Company's product candidates as discussed, *supra*, in ¶¶ 22-23.

37. Appended to the 2022 10-K as an exhibit was a signed certification pursuant to SOX by Defendants Brady and Greenberg, attesting that "[t]he information contained in the [2022 10-K] fairly presents, in all material respects, the financial condition and results of operations of [Aldeyra]."

38. Also on March 9, 2023, Aldeyra hosted an earnings call with investors and analysts to discuss the Company's Q4 2022 results (the "Q4 2022 Earnings Call"). During the scripted portion of the Q4 2022 Earnings Call, Defendant Brady stated, in relevant part:

> With regard to ADX-2191, last week, we were thrilled to announce that the FDA accepted for priority review our NDA for the treatment of primary vitreoretinal lymphoma, also known as ocular lymphoma. The FDA designed a PDUFA date of June 21, 2023, four months from the acceptance of the NDA for review. The NDA

is supported by a combination of more than 30 years of published literature on the safety and efficacy of methotrexate, the active ingredient of ADX-2191 for the treatment of ocular lymphoma. The submission is further supported by safety data from the recently completed Phase 3 GUARD trial of ADX-2191 in patients with proliferative vitreoretinopathy.

An estimated 300 to 600 patients in the United States are diagnosed with ocular lymphoma each year, and the median survival for newly diagnosed patients is less than five years. If approved, we expect to launch ADX-2191 in the United States in the second half of this year, which would make ADX-2191 the first FDA approved drug available for patient suffering from ocular lymphoma.

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2022 was a transformational year for Aldeyra, highlighted by the achievement of key clinical and regulatory milestones across our drug development pipeline, including the submission of two new drug applications. That momentum continues in 2023 as we move closer to our goal of validation of our platforms for immune-mediated systemic and retinal diseases.

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Through ADX-2191, we are creating a potential first-line therapy for rare retinal diseases without FDA approved therapies, beginning with ocular lymphoma, proliferative vitreoretinopathy and retinitis pigmentosa, all indications for which our drug has received FDA's orphan drug designation.

39. On May 4, 2023, Aldeyra issued a press release announcing the Company's Q1 2023 financial results and recent corporate highlights. The press release quoted Defendant Brady, stating, in relevant part, "Aldeyra continues to build a robust pipeline of novel drug candidates for the treatment of immune-mediated diseases," and "[m]ultiple regulatory and clinical catalysts are planned for the coming quarters, including PDUFA dates for ADX-2191 and reproxalap, top-line results from our Phase 2 clinical trials in retinitis pigmentosa and chronic cough, and top-line results from our Phase 3 INVIGORATE-2 trial in allergic conjunctivitis."

40. The statements referenced in ¶¶ 21-39 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically,

Defendants made false and/or misleading statements and/or failed to disclose that: (i) the ADX-2191 NDA did not include adequate and well-controlled investigations and thus failed to show substantial evidence of ADX-2191's effectiveness; (ii) as a result, the FDA was unlikely to approve the ADX-2191 NDA in its current form; (iii) accordingly, the Company had overstated ADX-2191's clinical and/or commercial prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

41. On June 21, 2023, Aldeyra issued a press release entitled "Aldeyra Therapeutics Provides Regulatory Update on ADX-2191." The press release stated, in relevant part:

- **Based on U.S. Food & Drug Administration (FDA) Determination of Lack of Adequate and Well Controlled Investigations in the Scientific Literature, Complete Response Letter Received for New Drug Application (NDA) of ADX-2191 (methotrexate injection, USP) for the Treatment of Primary Vitreoretinal Lymphoma (PVRL)**
- **Due to Shortage of Methotrexate, Lack of Approved Therapy for PVRL, and Inbound Requests for ADX-2191, Expanded Access Program Planned to be Discussed with FDA**

> [Aldeyra . . .] today announced receipt of a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the 505(b)(2) New Drug Application (NDA) of ADX-2191 (methotrexate for injection, USP), an investigational drug candidate, for the treatment of primary vitreoretinal lymphoma (PVRL). Although no safety or manufacturing issues with ADX-2191 were identified, the FDA stated that there was a "lack of substantial evidence of effectiveness" due to "a lack of adequate and well-controlled investigations" in the literature-based NDA submission. Based on prior discussions with the FDA, Aldeyra did not conduct any clinical trials of ADX-2191 in PVRL.
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> "While we appreciate the FDA's position with respect to providing evidence from adequate and controlled trials, we do not currently believe that randomized clinical trials of ADX-2191 in PVRL, a rare and fatal cancer with no approved therapy, are feasible," stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra Therapeutics. "Given the current shortage of methotrexate, the lack of approved therapy for PVRL, and the desire to avoid potential safety risks associated with ocular injection of compounded formulations, we look forward to discussing with the FDA the potential for making ADX-2191 available to PVRL patients under an Expanded Access Program."

> PVRL is a rare, high-grade, aggressive cancer, with a median survival of less than five years.[] Methotrexate, the compounded intravitreal injection of which is the standard of care for the treatment of PVRL,2 is currently in shortage, per the FDA Drug Shortages database. An Expanded Access Program allows for access to treatment options for serious diseases when other therapeutic options are not available. Aldeyra plans to discuss ADX-2191 for the treatment of PVRL with the FDA, including the potential to make ADX-2191 accessible to PVRL patients under an Expanded Access Program protocol.

42. On this news, Aldeyra's stock price fell $2.92 per share, or 27.44%, to close at $7.72 per share on June 21, 2023.

43. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

44. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Aldeyra securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

45. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aldeyra securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may

be identified from records maintained by Aldeyra or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

46. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

47. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

48. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Aldeyra;
- whether the Individual Defendants caused Aldeyra to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Aldeyra securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

49. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the

Damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

50. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Aldeyra securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Aldeyra securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

51. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

52. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

53. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

54. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

55. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Aldeyra securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Aldeyra securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

56. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Aldeyra securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Aldeyra's finances and business prospects.

57. By virtue of their positions at Aldeyra, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

58. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Aldeyra, the Individual Defendants had knowledge of the details of Aldeyra's internal affairs.

59. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Aldeyra. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Aldeyra's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Aldeyra securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Aldeyra's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise

acquired Aldeyra securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

60. During the Class Period, Aldeyra securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Aldeyra securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Aldeyra securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Aldeyra securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

61. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

62. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

63. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

64. During the Class Period, the Individual Defendants participated in the operation and management of Aldeyra, and conducted and participated, directly and indirectly, in the conduct of Aldeyra's business affairs. Because of their senior positions, they knew the adverse non-public information about Aldeyra's misstatement of income and expenses and false financial statements.

65. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Aldeyra's financial condition and results of operations, and to correct promptly any public statements issued by Aldeyra which had become materially false or misleading.

66. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Aldeyra disseminated in the marketplace during the Class Period concerning Aldeyra's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Aldeyra to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Aldeyra within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Aldeyra securities.

67. Each of the Individual Defendants, therefore, acted as a controlling person of Aldeyra. By reason of their senior management positions and/or being directors of Aldeyra, each

of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Aldeyra to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Aldeyra and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

68. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Aldeyra.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 31, 2023

Respectfully submitted,