Aldeyra Therapeutics Reports Full-Year 2022 Financial Results and Recent Corporate Highlights

March 9, 2023

- *NDA Priority Review PDUFA Date for ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma is June 21, 2023*
- *NDA PDUFA Date for Reproxalap for the Treatment of Dry Eye Disease is November 23, 2023*
- *Top-Line Results from the Phase 3 INVIGORATE-2 Trial of Reproxalap in Allergic Conjunctivitis Expected in the First Half of 2023*
- *Top-Line Results from the Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa Expected in the First Half of 2023*
- *Top-Line Results from the Phase 2 Clinical Trial of ADX-629 in Chronic Cough Expected in the First Half of 2023*
- *Cash, Cash Equivalents, and Marketable Securities of $174.3 Million as of December 31, 2022*
- *Management to Host Conference Call at 8:00 a.m. ET Today*

LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 9, 2023-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today reported recent corporate highlights and financial results for the year ended December 31, 2022.

“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 Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “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.
- **FDA Accepted for Review NDA of Reproxalap for the Treatment of Signs and Symptoms of Dry Eye Disease:** The NDA submission of topical ocular reproxalap, a first-in-class investigational new drug candidate, is supported by previously announced safety and efficacy results from five adequate and well-controlled clinical trials encompassing data for ocular dryness symptom score, ocular redness, Schirmer test, and Schirmer test ≥10 mm responder analysis. The NDA includes activity ranging from within minutes of drug administration to up to 12 weeks of treatment, crossover and parallel-group clinical trial designs, and assessment in dry eye chamber challenge and natural environment settings. The FDA assigned a PDUFA date of November 23, 2023. The FDA noted that no potential filing review issues had been identified, and that an advisory committee meeting was not currently planned.
- **Positive Top-Line Results Announced from the 12-Month Safety Clinical Trial of Reproxalap in Dry Eye Disease:** Treatment-related serious adverse events in ocular safety were not observed in any patient. Ocular safety events were similar across reproxalap and vehicle treatment groups. Consistent with prior experience with reproxalap and other topical ocular medications, the most common adverse event in reproxalap-treated patients was mild and transient instillation site irritation. In a post-hoc analysis, reproxalap was statistically superior to vehicle in improvement from baseline in distance visual acuity, potentially representing the first demonstration of improvement in distance visual acuity with a topically administered therapy.
- **Positive Top-Line Results Announced from the Phase 2 Clinical Trial of ADX-629 in Acute Alcoholic Hepatitis:** ADX-629, a first-in-class orally administered investigational RASP modulator, demonstrated target engagement and improvement in the signs of alcohol intoxication in a sequence-randomized, double-masked, placebo-controlled crossover Phase 2 clinical trial. Relative to placebo, ADX-629 reduced dermal flushing (P=0.0007); increased Romberg test balance time (P=0.02); and lowered levels of total cholesterol (P=0.02), LDL (P=0.047), and the ethanol RASP metabolite acetaldehyde (P=0.03) following acute exposure to alcohol. Both ADX-629 and placebo were well tolerated, and no safety

concerns were noted.

- **Phase 2 Clinical Trials Initiated for ADX-629 in Systemic Immune-Mediated Diseases:** Aldeyra initiated Phase 2 clinical trials evaluating the safety and efficacy of ADX-629 for the treatment of atopic dermatitis, idiopathic nephrotic syndrome, and Sjögren-Larsson Syndrome.

Upcoming Planned Clinical and Regulatory Milestones

- **Results from the Phase 3 INVIGORATE-2 Trial of Reproxalap in Allergic Conjunctivitis:** Top-line results from the Phase 3 clinical trial of reproxalap in patients with allergic conjunctivitis are expected in the first half of 2023. The Phase 3 INVIGORATE Trial in allergic conjunctivitis, announced in April 2021, met the primary endpoint and all secondary endpoints.
- **Results from the Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa:** Top-line results from the Phase 2 clinical trial of ADX-2191 in patients with retinitis pigmentosa, a rare group of sight-threatening retinal diseases with no approved therapy, are expected in the first half of 2023.
- **Results from Phase 2 Clinical Trials of ADX-629:** Top-line results from the Phase 2 clinical trial of ADX-629 in chronic cough are expected in the first half of 2023. Additionally, top-line results from Phase 2 clinical trials of ADX-629 in atopic dermatitis (Part 1), idiopathic nephrotic syndrome (Part 1), and Sjögren-Larsson Syndrome are expected in the second half of 2023.
- **Type C Meeting with the FDA for ADX-2191 in Proliferative Vitreoretinopathy:** Aldeyra plans to conduct a Type C meeting with the FDA mid-2023 to discuss the completion of clinical development of ADX-2191 for the prevention of proliferative vitreoretinopathy.
- **Initiation of Clinical Trials of Next-Generation RASP-Modulator Drug Candidates for Systemic Immune-Mediated Diseases and Geographic Atrophy:** Pending completion of Investigational New Drug requirements, a Phase 1 clinical trial of orally administered ADX-246 for the treatment of systemic immune-mediated diseases, and a Phase 1/2 clinical trial of intravitreally injected ADX-248 for the treatment of geographic atrophy, a sight-threatening retinal disease, are expected to initiate in the second half of 2023 or early 2024.

Full-Year 2022 Financial Results

Cash, cash equivalents, and marketable securities as of December 31, 2022 were $174.3 million. Based on its current operating plan, Aldeyra believes that existing cash, cash equivalents, and marketable securities will be sufficient to fund currently projected operating expenses into the second half of 2024, including the initial commercialization and launch plans for reproxalap and ADX-2191, if approved, and continued early and late-stage development of Aldeyra's product candidates in ocular and systemic immune-mediated diseases.

Net loss for the year ended December 31, 2022 was $62.0 million, or $1.06 per share, compared with a net loss of $57.8 million, or $1.07 per share, for the comparable period of 2021. Losses have resulted from the costs of clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses for the year ended December 31, 2022 were $47.3 million, compared with $44.9 million for the same period in 2021. The increase of $2.4 million is primarily related to an increase in our drug product manufacturing expenditures, personnel costs, consulting expenditures, and external preclinical development costs, partially offset by a decrease in our external clinical development costs.

General and administrative expenses for the year ended December 31, 2022 were $15.4 million, compared with $11.3 million for the same period in 2021. The increase of $4.1 million was primarily related to higher consulting expenditures and personnel costs.

Total operating expenses for the year ended December 31, 2022 were $62.7 million, compared with total operating expenses of $56.2 million for the same period in 2021.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss recent corporate highlights and financial results for the year ended December 31, 2022. The dial-in numbers are (833) 470-1428 for domestic callers and (404) 975-4839 for international callers. The access code is **202679**. Please dial in at least 10 minutes prior to the start time.

A live webcast of the conference call can be accessed via the Investors & Media page of the Aldeyra website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the website for 90 days.

About Aldeyra

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. Our approach is to 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 regarding the likelihood and timing of the FDA's potential approval of the NDAs for reproxalap and ADX-2191 by the respective PDUFA dates, or at any other time, and the adequacy of the data included in the NDA submissions; the expectation around any potential future request by the FDA to hold an advisory committee meeting related to the NDAs; the anticipated timing of enrollment and results from Aldeyra's clinical trials; expectations regarding the results of scheduled and planned pre-NDA meetings; the post-hoc analysis of the 12-month safety clinical trial and the potential to demonstrate distance visual acuity improvement in adults, expectations regarding evidence of acuity improvements and differentiation of reproxalap, if approved for sale, from other therapeutic options; and Aldeyra's projected cash runway. 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, requiring additional clinical trials or data prior to review or approval 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; the current and potential future impact of the COVID-19 pandemic on Aldeyra's business, results of operations, and financial position; 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, 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 set forth 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 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.

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 144,419,364	$ 104,790,989
Cash equivalent - reverse repurchase agreements	—	125,000,000
Marketable securities	29,881,520	—
Prepaid expenses and other current assets	6,722,229	2,961,781
Total current assets	181,023,113	232,752,770
Right-of-use assets	249,265	351,863
Fixed assets, net	19,279	32,487
Total assets	$ 181,291,657	$ 233,137,120
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 133,625	$ 1,019,702
Accrued expenses	14,065,885	10,523,353
Current portion of long-term debt	911,763	—
Current portion of operating lease liabilities	249,265	229,607

Total current liabilities	15,360,538	11,772,662
Operating lease liabilities, long-term	—	125,232
Long-term debt, net of current portion	14,923,090	15,503,703
Total liabilities	30,283,628	27,401,597
Stockholders' equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding	—	—
Common stock, voting, $0.001 par value; 150,000,000 authorized and 58,560,078 and 58,081,215 shares issued and outstanding, respectively	58,560	58,081
Additional paid-in capital	507,770,045	500,369,444
Accumulated other comprehensive loss	(103,938)	—
Accumulated deficit	(356,716,638)	(294,692,002)
Total stockholders' equity	151,008,029	205,735,523
Total liabilities and stockholders' equity	$ 181,291,657	$ 233,137,120

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 47,306,066	$ 44,936,532
General and administrative	15,373,921	11,283,004
Loss from operations	(62,679,987)	(56,219,536)
Other income (expense):		
Interest income	2,349,449	185,363
Interest expense	(1,694,098)	(1,742,101)
Total other income (expense), net	655,351	(1,556,738)
Net loss	$(62,024,636)	$(57,776,274)
Net loss per share - basic and diluted	$ (1.06)	$ (1.07)
Weighted average common shares outstanding - basic and diluted	58,405,897	54,042,103

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Source: Aldeyra Therapeutics, Inc.