Aldeyra Therapeutics Reports Third-Quarter 2022 Financial Results and Recent Corporate Highlights

November 10, 2022

- *New Drug Application (NDA) Submission of Reproxalap for the Treatment of Dry Eye Disease on Schedule for the Fourth Quarter of 2022*
- *Pre-NDA Meeting with the U.S. Food and Drug Administration (FDA) Scheduled for the Fourth Quarter of 2022 to Discuss NDA Submission of ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma*
- *Top-Line Results from the Phase 2 Clinical Trial of Oral RASP Modulator ADX-629 in Acute Alcoholic Hepatitis Expected by the End of 2022*
- *Type C Meeting with the FDA Planned for the First Half of 2023 to Discuss Completion of Clinical Development of ADX-2191 for the Treatment of Proliferative Vitreoretinopathy*
- *Top-Line Results from the Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa Expected in the First Half of 2023*
- *Cash, Cash Equivalents, and Marketable Securities Exceeding $185 Million as of September 30, 2022*
- *Management to Host Conference Call at 8:00 a.m. ET Today*

LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 10, 2022-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases, today reported recent corporate highlights and financial results for the quarter ended September 30, 2022.

“Now 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,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra.

Recent Corporate Highlights

- **Pre-NDA Meeting with the FDA for Reproxalap in Dry Eye Disease:** Following the receipt of official minutes from its pre-NDA meeting with the FDA, Aldeyra remains on schedule to submit an NDA requesting marketing approval of the novel RASP modulator reproxalap in the fourth quarter of 2022. With results from five adequate and well-controlled completed clinical trials, Aldeyra intends to submit the NDA with data for ocular dryness symptom score, ocular redness, Schirmer test, and Schirmer test ≥10 mm responder analysis. The NDA efficacy package is expected to include 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. In addition to efficacy data, Aldeyra plans to submit up to 12 months of reproxalap safety data. Topical ocular reproxalap has been studied in more than 2,000 patients with no observed clinically significant safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.
- **Results from the Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy:** ADX-2191 was statistically superior to historical control[1] for the prevention of retinal detachment due to proliferative vitreoretinopathy over six months (P=0.024). Although not statistically powered for secondary or exploratory endpoints, the results of the GUARD Trial demonstrated numerical superiority of ADX-2191 over routine surgical care in reducing the dichotomous endpoints of retinal detachment rate over six months, hypotony (low intraocular pressure), complete retinal attachment by six months, macular attachment by six months, and epiretinal membrane formation (overall P=0.047). The most common adverse event associated with ADX-2191 treatment was punctate keratitis, a well-known side effect of intravitreal methotrexate, that was most commonly mild in severity. Across all other treatment-emergent adverse events occurring in at least 10% of patients in either treatment arm, relative to patients treated with routine surgical care, ADX-2191-treated patients had numerically fewer side effects, including pain, cystoid macular edema, corneal edema, macular fibrosis, corneal epithelial defects, anterior uveitis, ocular hypertension, and post-operative inflammation (overall P=0.0002).

Additional Upcoming Planned Clinical and Regulatory Milestones

- **Pre-NDA Meeting with the FDA for ADX-2191 in Primary Vitreoretinal Lymphoma:** 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.
- **Type C meeting with the FDA for ADX-2191 in Proliferative Vitreoretinopathy:** Aldeyra plans to conduct a Type C meeting with the FDA in the first half of 2023 to discuss the completion of clinical development of ADX-2191 for the prevention of proliferative vitreoretinopathy.

- **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 are expected in the first half of 2023.
- **Results from Phase 2 Clinical Trials of ADX-629 in Systemic Immune-Mediated Diseases:** By the end of this year, Aldeyra expects to report top-line results from a Phase 2 clinical trial in acute alcoholic hepatitis, and to initiate Phase 2 clinical trials in Sjögren-Larsson Syndrome and minimal change disease. Top-line results from the ongoing Phase 2 clinical trial of ADX-629 in chronic cough are anticipated in the first half of 2023.

Third-Quarter 2022 Financial Results

Cash, cash equivalents, and marketable securities as of September 30, 2022 were $185.3 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 through the end of 2023, including NDA submissions and initial commercialization of 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 three months ended September 30, 2022 was $14.6 million, or $0.25 per share, compared with a net loss of $15.8 million, or $0.27 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 three months ended September 30, 2022 were $11.5 million, compared with $12.9 million for the same period in 2021. The decrease of $1.4 million is primarily related to a decrease in external clinical development costs, offset by an increase in Aldeyra's external preclinical development costs, drug product manufacturing expenditures, personnel costs, and consulting expenditures.

General and administrative expenses for the three months ended September 30, 2022 were $3.2 million, compared with $2.5 million for the same period in 2021. The increase of $0.7 million was primarily related to higher personnel costs and consulting expenditures.

Total operating expenses for the three months ended September 30, 2022 were $14.8 million, compared with total operating expenses of $15.4 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 quarter ended September 30, 2022. The dial-in numbers are (844) 200-6205 for domestic callers and (929) 526-1599 for international callers. The access code is **048610**. 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 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 the timing of planned NDA submissions; the anticipated timing of enrollment and results from Aldeyra's clinical trials; expectations regarding the results of scheduled and planned pre-NDA meetings, including the FDA's acceptance of Aldeyra's post-hoc review of data, the FDA's agreement with Aldeyra's methods of analyzing data and the FDA's agreement that data from the crossover clinical trial can be used to support the safety or efficacy of reproxalap; 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, 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; 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 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 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; 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 June 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, expected to be filed with the SEC in the fourth quarter of 2022.

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

	September 30, 2022	December 31, 2021
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 107,150,541	$ 104,790,989
Cash equivalent - reverse repurchase agreements	21,500,000	125,000,000
Marketable securities	56,678,860	—
Prepaid expenses and other current assets	4,153,721	2,961,781
Total current assets	189,483,122	232,752,770
Right-of-use assets	181,943	351,863
Fixed assets, net	26,660	32,487
Total assets	$ 189,691,725	$ 233,137,120
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,306,926	$ 1,019,702
Accrued expenses	10,254,451	10,523,353
Current portion of long-term debt	12,449,058	—
Current portion of operating lease liabilities	184,599	229,607
Total current liabilities	24,195,034	11,772,662
Operating lease liabilities, long-term	—	125,232
Long-term debt, net of current portion	3,303,042	15,503,703
Total liabilities	27,498,076	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	506,235,298	500,369,444
Accumulated other comprehensive loss	(285,733)	—
Accumulated deficit	(343,814,476)	(294,692,002)
Total stockholders' equity	162,193,649	205,735,523
Total liabilities and stockholders' equity	$ 189,691,725	$ 233,137,120

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 11,539,620	$ 12,894,344	$ 38,344,594	$ 32,095,132
General and administrative	3,244,936	2,546,807	10,638,602	8,720,161
Loss from operations	(14,784,556)	(15,441,151)	(48,983,196)	(40,815,293)
Other income (expense):				
Interest income	648,242	59,306	1,094,001	122,732
Interest expense	(416,917)	(413,110)	(1,233,279)	(1,329,166)
Total other income (expense), net	231,325	(353,804)	(139,278)	(1,206,434)
Net loss	$ (14,553,231)	$ (15,794,955)	$ (49,122,474)	$ (42,021,727)
Net loss per share - basic and diluted	$ (0.25)	$ (0.27)	$ (0.84)	$ (0.80)
Weighted average common shares outstanding - basic and diluted	58,457,863	58,019,099	58,352,991	52,688,846

[1] Ophthalmology 124(6):757-767, 2017; Archives of Ophthalmology 25(9):1161-7, 2007.

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